

5 **SURGICAL STAPLE-CLIP AND APPLIER**

This is a non-provisional application claiming the priority of provisional application Serial No. 60/434,344, filed on December 17, 2002, entitled "Surgical Staple-Clip and Applier," which is fully incorporated herein by reference.

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**BACKGROUND OF THE INVENTION****Field of the Invention**

This invention generally relates to medical devices and, more specifically, to a staple-clip and applier adapted for use in surgical procedures.

15 **Discussion of the Prior Art**

Clips and staples are widely used in many surgical procedures such as occlusion, ligation and fixation of various body tissues and vessels. Clips are generally U-shaped, open-ended wires that are positioned around a target tissue and clamped together to constrict or occlude the tissue. A clip applier is typically used for applying the clips. Clip appliers can be configured for applying a single clip or multiple clips in both open and minimally invasive or laparoscopic surgeries. The individual clips are provided in a loading cartridge or rack of a clip applier. With minimally invasive surgery, a clip applier must be able to deliver clips through a small access port or trocar having a diameter of about 10 mm to 20 12 mm. Accordingly, the size of a deliverable laparoscopic clip must be smaller than the inside diameter of the trocar through which it is introduced. Typically, a 25

12 mm clip applicator is capable of delivering a clip that is no longer than 7-8 mm. It is not uncommon for laparoscopic surgeons to discover that even the largest clip available is undersized for a particular surgical procedure. Moreover, clips will occasionally move about or slip off the tissue to which they have been applied.

- 5 In some cases, a surgeon may apply an excessive compressive force to the clip and tissue to minimize movement or slippage of the clip. This excessive compression may cause necrosis of tissue since nutrition to the tissue is interrupted or eliminated.

- 10 Staples are also widely used in many surgical procedures to constrict or occlude a body tissue or vessel. A surgical staple typically includes a pair of penetrating legs connected by a base portion. Surgical staples are applied using a stapler, which compresses the penetrating legs as the legs advance through the body tissue and are bent against an opposing jaw of the stapler to secure the staple to the body tissue. A feature of the staple is it defines open portions that
- 15 provide nourishment to the tissue even when the staple is bent. Surgical staples have proved to be effective, however, the staplers used for applying the staples are often bulky and require a very strong closing or compressing force, which is not ideal for minimally invasive or laparoscopic surgeries. As such, it is desirable to find a staple/clip providing good traction to prevent movement and slippage
- 20 while requiring only a force to close or compress the staple/clip. Specifically, it is desirable to have a staple/clip where the force required to constrict or occlude a body tissue is separate from the force required to secure and maintain the device in position. The staple-clip would provide good traction while maintain proper

nourishment to the body tissue. It is advantageous to use the staple/clip, for example, to secure the renal vessel in donor nephrectomy.

### **SUMMARY OF THE INVENTION**

5           The present invention is directed to a surgical staple-clip for use in a wide range of surgical procedures. The staple-clip comprises a plurality of individual elements including a clip component and a securing or fixation member connected with the clip component to form a composite staple-clip. The composite staple-clip may be configured for use in both open and minimally  
10   invasive or laparoscopic surgeries. The staple-clip may be introduced to a surgical site in an un-assembled condition through a small port or trocar. An applier for the staple-clip comprising a pair of opposed jaw-like channels is provided to position and apply the clip component and the securing member. The clip component is positioned around a target tissue and is compressed or  
15   clamped upon the tissue using only the force required for a specific surgical procedure such as occlusion, ligation or fixation. When the clip component is properly applied and the desired effects are observed, the securing member is urged forward and over the clip component to secure the staple-clip.

          In one aspect of the invention, the clip component includes traction  
20   enhancement features including surface interruptions, bumps, valleys, ridges and the like. In another aspect of the invention, the clip component includes tissue-penetrating features similar to those of a staple. It is appreciated that with the staple-clip of the invention, the force required to constrict or occlude the tissue is

separate from the force required to secure and maintain the staple-clip in position. That is, only the compressive force needed to perform a specific surgical procedure such as occlusion, ligation or fixation is applied to the body tissue, and the force normally required to secure and maintain a clip of the prior art is not applied since traction and security are supplied by the clip component and securing member of the staple-clip. As a result, the body tissue is not over-compressed and nourishment to the body tissue is maintained.

Other aspects of the invention include thumb actuated clip appliers for use in hand assisted laparoscopy (HAL). In one embodiment, a clip applier includes a handle and a thumb actuated mechanism that is used to slidably release clips onto a body tissue or vessel by sliding the thumb actuated mechanism forward and backward using only one hand. This design closes the jaws around the body tissue or vessel and allows a closed clip to slide into position. In another embodiment, a clip is provided having a first arm and a second arm folded over the first arm. The first arm includes a latch mechanism such as an inwardly turned portion or hook at its distal end that is configured to interlock or mate with a distal end of the second arm when the arms are clamped together. The latch mechanism operates in a similar way to a hair clip and responds to thumb pressure. An operator may single-handedly access the clip and slide it onto a body tissue or vessel as needed. The arms of the clip may include tissue-penetrating elements on the inner, opposed faces of the arms.

In another aspect of the invention, a two-stage clip is disclosed having a clip component and a staple component for securing the clip after it has been

properly positioned. The clip component is formed from a first piece of material and includes opposed arms, each of which includes openings allowing penetration of legs of the staple component. The staple component is formed from a second piece of material and is used to puncture a body tissue or vessel and to interlock the clip component. The arms of the clip component may include a latch mechanism at the distal ends to mate with each other when the arms are closed or clamped together. During use, the first stage closes the arms of the clip. After the first stage, the clip can still be safely removed. The second stage secures the clip permanently onto the body tissue or vessel by applying the staple component to the clip component. In another embodiment, a two-stage clip is formed entirely from a single piece of material and includes a first arm and an opposed second arm. The second arm further includes securing elements, all of which are formed as an integral, one-piece construction. With this construction, the securing elements may still remain open after the first stage when the arms are clamped upon a body tissue or vessel. A second action then presses the securing elements into the body tissue or vessel.

These and other features and advantages of the invention will become more apparent with a discussion of preferred embodiments in reference to the associated drawings.

#### **DESCRIPTION OF THE DRAWINGS**

FIGS. 1(a) and 1(b) illustrate a typical surgical clip in an open condition and a closed condition, respectively;

FIG. 2 illustrates the movement and slippage of a typical surgical clip;

FIGS. 3(a) and 3(b) illustrate a typical surgical staple in an open condition and a closed condition, respectively;

FIGS. 4(a) and 4(b) illustrate a typical arrangement of open and closed  
5 surgical staples, respectively;

FIGS. 5(a) and 5(b) illustrate a typical surgical clip applier and staple  
applier, respectively;

FIG. 6(a) is a perspective view of the clip components and securing  
member of the staple-clip in accordance with an embodiment of the invention;

10 FIG. 6(b) is a perspective view of the assembled staple-clip of FIG. 6(a);

FIG. 7 is a perspective view of the assembled staple-clip of FIG. 6(b)  
placed upon a body conduit or passage;

FIG. 8 is a perspective view of the staple-clip and applier configured for  
use in a minimally invasive surgical procedure;

15 FIGS. 9(a), 9(c), 9(e) and 9(g) are side views of the staple-clip of the  
invention in an open, closing, closed and locked condition, respectively;

FIGS. 9(b), 9(d), 9(f) and 9(h) are end views of the staple-clip of FIGS.  
9(a), 9(c), 9(e) and 9(g), respectively;

FIGS. 10(a) and 10(b) are perspective views of a clip in an open and  
20 closed condition, respectively, having a monolithic construction in accordance  
with another embodiment of the invention;

FIGS. 10(c) and 10(d) are side views of the clip of FIGS. 10(a) and 10(b),  
respectively, having pointed tissue-penetrating elements;

FIGS. 10(e) and 10(f) are end views of the clip of FIGS. 10(c) and 10(d), respectively;

FIGS. 11(a) and 11(b) are side views of the staple-clip before and after placement upon a body conduit or passage, respectively;

5        FIGS. 11(c) and 11(d) are end views of the staple-clip of FIGS. 11(a) and 11(b), respectively;

FIGS. 12(a) and 12(b) are schematic side views of a staple-clip applicator in a closed and open condition, respectively;

10        FIGS. 12(c) and 12(d) are front, end views of the staple-clip applicator of FIGS. 12(a) and 12(b), respectively;

FIGS. 13(a) and 13(b) are perspective views of the tissue contacting face portions of a staple-clip in another aspect of the invention;

FIG. 14 illustrates the sequence of placing the securing member upon the tissue-engaging members of the staple-clip of the invention;

15        FIGS. 15(a), 15(b) and 15(c) illustrate the invention sized and configured to pass through a small trocar port in a first condition, second condition and final condition, respectively;

FIG. 16 illustrates placement of a single staple-clip of the invention;

FIG. 17 illustrates parallel placement of the staple-clips of the invention;

20        FIG. 18 illustrates parallel placement of the staple-clips of the invention with a cutting element placed between the staple-clips;

FIG. 19 illustrates a laparoscopic stapler configured for use in donor nephrectomy in accordance with another aspect of the invention;

FIGS. 20(a) – 20(e) illustrate various thumb actuated clip appliers for use in hand assisted laparoscopy (HAL) in accordance with additional aspects of the invention;

FIG. 21 illustrates a spring like coil for suturing a body tissue or vessel in accordance with another aspect of the invention;

FIG. 22 illustrates a plurality of staples formed from a single piece of material in accordance with another aspect of the invention;

FIG. 23 illustrates a temporary HAL clamp for use in donor nephrectomy in accordance with another aspect of the invention;

FIGS. 24 – 26 illustrate various two-stage staple-clips in accordance with additional aspects of the invention; and

FIG. 27 illustrates a holder to press a body tissue flat and to provide clearance during placement of a staple-clip having sharp features.

## **DESCRIPTION OF PREFERRED EMBODIMENTS**

### **AND BEST MODE OF THE INVENTION**

FIGS. 1 and 2 illustrate a surgical clip 10 of the prior art having a generally open shape including a first leg 15, a second leg 20 and a base 30 connecting the first leg 15 and the second leg 20. The clip 10 can be positioned around a body conduit or passage, e.g., a blood vessel, and compressed using a clip applier 150 as illustrated in FIG. 5(a). The clip applier 150 generally comprises an elongate shaft 155, sized and configured to fit through a surgical trocar port, a distal end 160 having a pair of opposed jaws 165, 167 and a proximal end 170



having a handle 180 to open and close the jaws 165, 167. The clip 10, held in an open condition, is supplied to the jaws 165, 167 either automatically or manually.

The clip 10 is advanced to a desired site and subsequently closed or compressed. With the first and second legs 15 and 20 properly formed, the jaws 165, 167 can be opened and moved away from the tissue leaving the clip 10 clamped around the tissue. The clip 10 derives its strength from the material from which it is made. The material chosen must be sufficiently malleable to allow the clip to be compressed as illustrated in FIG. 1(b) while preventing spring-back of the material after application of a compressive force.

There are many factors that must be considered in applying a surgical clip to a body tissue or vessel. First, the clip must be sufficiently wide to completely encompass the tissue. As illustrated in FIG. 1(a), the clip 10 must have an open area 50 that is wide enough to encompass the target tissue. Second, the clip must be compressible with a reasonable application force, i.e., a force that an operator feels comfortable applying to the body tissue. Third, the clip, once applied, must not move from the location where it was applied. As illustrated in FIG. 2, the clip 10 must not slip along axes 80(a) or 80(b) or slip off of body vessel 60. A fourth factor is that the clip 10 should not compress the body tissue so much that it constricts, interrupts or destroys the nourishment of the tissue.

As can be seen, the above factors of clip-based ligation or fixation are difficult to achieve using a single wire-formed clip. Moreover, the issues of compression and traction must be separated if proper nourishment of the tissue is to be preserved while maintaining a secure placement of the clip.

Surgical staples are another device that is commonly used for occlusion, ligation and fixation of body tissues and vessels. Referring to FIG. 3(a), a typical surgical staple 100 comprises generally straight, penetrating leg portions 110 and 120 connected together by a base portion 130. As the penetrating leg portions 110, 120 are applied to a body tissue or vessel, the leg portions advance through the tissue and are bent against the opposing jaw of the stapler and toward each other as illustrated in FIG. 3(b). The bending of the staple 100 forms a confinement of the body tissue that is, for the most part, independent of the compression of the tissue itself. FIG. 5(b) illustrates a laparoscopic stapler 190 that operates in much the same way as a clip applier. During use, the stapler 190 is advanced over a portion of body tissue and is compressed to deliver at least one, and more often several, penetrating surgical staples. See, for example, FIGS. 4(a) and 4(b). The compressed surgical staple 100 has a general shape of the capital letter "B" where fluid nourishment of the tissue is provided through open portions 140 of the folded staple 100. Surgical staples have proved to be effective and are a standard in surgery. However, the staplers used for applying the staples are often bulky and require a very strong closing or compressing force, which is not ideal for minimally invasive or laparoscopic surgeries. Accordingly, there is a need in the art for a device having features and advantages of both the staple and clip. The staple/clip would provide good traction to prevent the device from moving or dislodging from the body tissue while maintaining proper nourishment to the tissue. In addition, the force required to constrict or occlude the body tissue would be separated from the

force required to secure and maintain the device in position. Specifically, the portion of tissue to be treated would not be compressed more than is necessary to achieve the desired result.

FIG. 6(a) illustrates a surgical staple-clip 200 in accordance with a first  
5 embodiment of the invention. The staple-clip 200 comprises a first tissue-engaging member 205, a second tissue-engaging member 210 opposed to the first tissue-engaging member 205, and a securing or fixation member 220 for securing the first and second tissue-engaging members 205, 210. The first  
10 tissue-engaging member 205 comprises generally opposed walls 230, 232 and a connecting wall 234 that together define an elongate channel 236. The second tissue-engaging member 210 is similar to the first tissue-engaging member 205 and comprises generally opposed walls 240, 242 and a connecting wall 244 that together define an elongate channel 246. The tissue-engaging members 205, 210 are normally held such that the front faces of the connecting walls 234, 244,  
15 respectively, are opposed to each other. The opposing front faces of the connecting walls 234, 244 may include a plurality of tissue-penetrating elements 238, 248, respectively.

An advantage of the staple-clip of the invention is it provides good traction without requiring an excessive compressive force to be applied to the staple-clip.  
20 In particular, the securing member 220 is sized and configured to slide into the elongate channels 236, 246 to securely clamp the tissue-engaging members 205, 210 around a body tissue or vessel with minimal compressive force. More specifically, the force required to secure and maintain the staple-clip (to provide

adequate traction) is independent from the force required to constrict or occlude a body tissue or vessel. With the staple-clip of the invention, only the compressive force needed to perform a specific surgical procedure such as occlusion, ligation or fixation is applied to the body tissue, and the force normally required to secure and maintain a clip of the prior art is not applied since traction and security are supplied by the tissue-engaging members 205, 210. In other words, the staple-clip of the present invention provides the necessary traction without requiring an excessive compressive force to keep the staple-clip from moving or becoming loose. As a result, nourishment of the lightly compressed tissue is maintained and tissue necrosis due to over-compression is eliminated.

In another aspect of the invention, the tissue-engaging members include traction enhancing features including bumps, ridges, slots, holes, etc. as generally illustrated in FIGS. 13(a) and 13(b). The traction enhancing features are sized and configured to grip tissue and provide traction and security beyond that which might be achieved by over-compressing a typical clip. The securing member 220 may be a spring-clip or a deformable clip acting as a retention member and providing a uniform pressure across the occluded tissue or vessel to prevent loosening of the staple-clip 200 over time as illustrated in FIGS. 7, 9(a) – 9(h) and 14. The tissue-penetrating elements 238, 248 are configured to penetrate the tissue and to prevent the tissue from moving or sliding when clamped as illustrated in FIGS. 11(a) – 11(d), 16 and 17.

It is appreciated that the connecting walls 234, 244 and the respective tissue-penetrating elements 238, 248 may be formed as an integral, one-piece

construction. It is further appreciated that the number of rows of tissue-  
penetrating elements and the number of tissue-penetrating elements per row  
may vary according to each application and the shape and size of the clip and  
body tissue. It is further noted that the tissue-penetrating elements in each row  
5 may be aligned or staggered as desired. The tissue-engaging members 205,210  
and the securing member 220 may have cross-sections of any configuration  
including polygonal, circular and elliptical configurations.

Referring to FIG. 10, there is shown a monolithic staple-clip 500 in  
accordance with another aspect of the invention. The monolithic staple-clip 500  
10 has a general shape of the capital letter "U". The staple-clip 500 comprises a  
first tissue-engaging portion or leg 505, an opposed second tissue-engaging  
portion or leg 510 and a deformable connecting portion 520 connecting the first  
and second tissue-engaging portions 505 and 510. Each of the opposing faces  
of the tissue-engaging portions 505, 510 comprises a plurality of tissue  
15 penetrating elements or protrusions 525, 530, respectively. The protrusions are  
sized and configured to penetrate tissue that is captured between the tissue-  
engaging portions and provide traction and security beyond that which might be  
achieved by over-compressing a typical clip. Similar to other aspects of the  
invention, only the force required to perform a specific surgical procedure such  
20 as occlusion, ligation or fixation is applied to a body tissue and the force  
previously needed to secure and maintain the clip is no longer applied.  
Nourishment of the lightly compressed tissue is thus maintained and tissue  
necrosis due to over-compression is eliminated.

The monolithic staple-clip 500 may be formed from a flat metal sheet that is die-cut, stamped or etched forming a first notched or toothed portion, a smooth connecting portion and a second notched or toothed portion. The notches or teeth of the first and second portions are then bent so as to extend in the same direction or plane and to form channels within the notches or teeth. The staple-clip is then formed in a U-shape by bending the connecting portion so that the notches or teeth of the two tissue-engaging portions are opposed. A preferred embodiment of the monolithic staple-clip comprises a malleable material such as Titanium or stainless steel. Other materials include any medically acceptable metal or plastic material that is ductile, malleable or deformable.

It is appreciated that the staple-clips of the invention can be applied to a body tissue or vessel using an applier 600 as illustrated in FIGS. 12(a) – 12(d). The staple-clip applier 600 generally comprises an elongate shaft 605, sized and configured to fit through a surgical trocar port, a distal end 610 having a pair of opposed jaws 615, 620, and a proximal end (not shown) having a handle to open and close the jaws 615, 620. The staple-clip applier 600 further comprises a sliding member 625 to advance the securing member 220 over the tissue-engaging members 205, 210 after closure of the jaws 615, 620 as further described below. The jaws 615, 620 operate to apply the tissue-engaging members 205, 210, respectively, around a target body tissue or vessel. The tissue-engaging members are supplied to the jaws either manually or automatically. With the tissue-engaging members 205, 210 properly placed, the jaws 615, 620 can be compressed using only the force required for a specific

surgical procedure such as occlusion, ligation or fixation. When the tissue-engaging members 205, 210 are properly applied, the sliding member 625 can then urge the securing member 220 forward and over the tissue-engaging members 205, 210 to secure the staple-clip 200 as illustrated in FIGS. 9(a) – 9(h), 11(a) – 11(d) and 14. The tissue-engaging members 205, 210 and securing member 220 may be introduced to a surgical site in an un-assembled condition through a small port or trocar. FIGS. 8 and 15(a) – 15(c) further illustrate the staple-clip and applier sized and configured for use in a minimally invasive or laparoscopic surgical procedure.

Multiple staple-clips may also be loaded in a staple-clip applier and advanced individually or simultaneously between the jaws. In the case of simultaneously applying the staple-clips, the applier must include a plurality of slots in the opposed jaws to receive the multiple staple-clips. A cutting member such as a blade may be included in the applier to be advanced between the staple-clips after they have been applied to transect the body tissue between the staple-clips as illustrated in FIGS. 17 and 18.

In another aspect of the invention, FIG. 19 depicts a traditional laparoscopic stapler 800 that is configured specifically for donor nephrectomy. The stapler 800 includes a plurality of rows of staples on the patient side 805 and a temporary clip 810 that substitutes for a typical set of staples on the kidney side 815. The stapler 800 operates like existing place and cut staplers with the exception that a temporary clip or clips 810 replace the set of staples on the kidney side 815. The temporary clip 810 may be a staple cartridge configured for

use in donor nephrectomy. An advantage of this configuration is it salvages a greater portion of the vessel for the transplant procedure.

Another aspect of the invention is directed to hand assisted laparoscopy (HAL), the widespread acceptance of which has created many opportunities for surgical advancement utilizing single hand procedures. FIGS. 20(a) – 20(e) illustrate thumb actuated clip appliers 850, 875 and 895 in accordance with the teachings of the invention. The clip applier 850 includes a handle 855 and a thumb actuated mechanism 860. An operator can slidably release clips 865 onto a vessel by sliding the thumb actuated mechanism 860 forward 870a and backward 870b using only one hand as illustrated in FIGS. 20(a) – 20(b). This design closes the jaws around the vessel and allows a closed clip to slide into position. The handle 855 also serves as a reservoir for additional clips 865. The clip 875 is also designed for HAL applications and includes a first arm 880 and a second arm 885 folded over the first arm 880. The first arm 880 includes a latch mechanism 890 such as an inwardly turned portion or hook at its distal end that is configured to interlock or mate with a distal end of the second arm 885 when the arms are clamped together. The latch mechanism 890 operates in a similar way to a hair clip and responds to thumb pressure. An operator may single-handedly access the clip 875 and slide it onto a body tissue or vessel as needed.

A plurality of clips 875 may be strung end-to-end in a clip sleeve 892 suspended through an open port. An advantage of the clip 875 is there is no instrument to misplace. The clip sleeve 892 holding the clips 875 can also be withdrawn or fed through any open port or trocar. The clip sleeve 892 can also



be designed to keep the clips 875 partially closed, enabling the use of smaller ports or trocars. The clip 895 as illustrated in FIG. 20(e) is similar to the clip 875 but further includes tissue-penetrating elements 898 on the inner faces of arms 896, 897. The clip 895 may also include a third arm 899 connecting the arms 896, 897.

In another aspect of the invention as illustrated in FIG. 21, a spring like coil 900 is used for suturing a body tissue or vessel in place of clips and staples. The spring like coil 900 is applied onto a body tissue or vessel 905 by using a stapler 910 having grooved jaws 910, 915. The spring like coil 900 is preferably loaded or twisted into one of the grooved jaws 910, 915, which is then compressed or clamped against the other grooved jaw to constrict or occlude the vessel 905. An advantage of this design is closure of the coil 900 provides a stitch like nature that replicates a uniformly applied suture. In one configuration, a single coil is inserted in place of each suture. It is appreciated that a single coil or multiple coils may be loaded into the grooved jaws of a stapler for each specific surgical procedure or closure.

In yet another aspect of the invention, FIG. 22 illustrates multiple staples 925 formed from a single piece of material 930 to reduce the high manufacturing costs associated with current stapler cartridges. These costs savings translate to increased margins or reduced product cost. Each of the staples 925 has an angled leg 935 and an inclined rail 940 for easy push up and closure by a stapler. The staples 925 all share a common portion 945, which allows the row of staples to be formed as an integral, one-piece construction. The staples 925 can also be

formed to offset each other and to emulate multiple rows. An advantage of this aspect of the invention is it provides a compact cartridge that is suitable for donor nephrectomy.

FIG. 23 illustrates a temporary HAL clamp 950 for use in donor  
5 nephrectomy in accordance with another aspect of the invention. The clamp 950 includes a tubular section 955 defining an opening 960 extending from a proximal end 965 to a distal end 970, and a lead-in wire 975 operably attached to the proximal end 965. The lead-in wire 975 is movable between an open position and a closed position. When closed, the lead-in wire 975 is slidably received and  
10 secured in the opening 960 of the tubular section 955. During use, an operator may manually wrap a vessel or vessels (e.g., the renal artery and vein can be cinched together into the clamp) around the lead-in wire 975 and secure the wire 975 in the opening 960 of the tubular section 955. The lead-in wire 975 may be bent against the wall of the tubular section 955 to further secure the vessel(s) for  
15 kidney removal and transport.

FIGS. 24, 25 and 26 illustrate two-stage clips 1010, 1020 and 1030, respectively, in accordance with additional embodiments of the invention. The clips 1010, 1020 and 1030 require an applier (not shown) for placement onto a body tissue or vessel. The clip 1010 includes a clip component 1011 and a  
20 staple 1012 for securing the clip after it has been properly positioned. The clip component 1011 is formed from a single wire and includes opposed arms 1013, 1014. Each of the arms 1013, 1014 includes openings 1015, 1016, respectively, allowing penetration of legs 1017, 1018 of the staple 1012. The staple 1012 is

formed from a second wire and is used to puncture the body tissue or vessel and interlock the clip component 1011. The arms 1013, 1014 may include a latch mechanism at the distal ends to mate with each other when the arms are closed or clamped together. During use, the first stage closes the arms 1013, 1014 of the clip. After the first stage, the clip can still be safely removed. The second stage secures the clip permanently onto the body tissue or vessel by applying the staple 1012 to the clip component 1011.

The two-stage clip 1020 as shown in FIG. 25 is formed entirely from a single piece of material and includes a first arm 1021 and an opposed second arm 1022. The second arm 1022 further includes securing elements 1023, 1024, all of which are formed as an integral, one-piece construction. With this construction, the securing elements 1023, 1024 may still remain at an angle after the first stage (when the arms 1021 and 1022 are clamped upon a body tissue or vessel). A second action then presses the securing elements 1023, 1024 into the body tissue or vessel. The clip 1030 as shown in FIG. 26 is similar to the clip 1010 and includes a clip component 1031 and a staple component 1032 for securing the clip after it has been properly positioned. The clip component 1031 includes opposed arms 1013, 1014 defining openings 1035, 1036, respectively. The staple component 1032 includes opposed arms 1037, 1038 having tissue-securing elements 1039, 1040, respectively, which operate to secure the clip onto a body tissue or vessel through the openings 1035, 1036. The clip 1030 may be formed in sheet stock.

FIG. 27 illustrates a tissue holder 1100 for use with staple-clips that may include sharp features, e.g., tissue-penetrating elements, that can potentially injure tissue during a surgical procedure. In particular, the tissue holder 1100 is used to press a body tissue flat and to provide clearance during placement of a  
5 staple-clip.

Although exemplary embodiments of the invention have been shown and described, many alterations and modifications may be made by those having ordinary skill in the art without departing from the spirit and scope of the invention. Therefore, it must be understood that the illustrated embodiments  
10 have been set forth only for the purposes of examples and that they should not be taken as limiting the invention. In addition, the words used in this specification to describe the invention and its various embodiments are to be understood not only in the sense of their commonly defined meanings, but to include any special definition given in this specification.

**CLAIMS**

1. A medical device to constrict or occlude a body tissue or vessel,  
comprising:

5       a first tissue-engaging member 205 having opposed walls 230, 232 and a  
first connecting wall 234 defining a first elongate channel 236;

      a second tissue-engaging member 210 opposed to the first tissue-  
engaging member 205 having opposed walls 240, 242 and a second connecting  
wall 244 defining a second elongate channel 246; and

10       a securing member 220 for securing the first and the second tissue-  
engaging members 205, 210 such that front faces of the first and the second  
connecting walls 234, 244 are opposed to each other.

2. The medical device of claim 1, wherein each of the front faces of the  
first and the second connecting walls 234, 244 includes a plurality of tissue-  
penetrating elements 238, 248.

3. The medical device of claim 1, wherein the securing member 220 is  
sized and configured to slide into the first and the second elongate channels 236,  
246 to securely clamp the first and the second tissue-engaging members 205,  
210 around the body tissue or vessel with minimal compressive force.

5           4. The medical device of claim 3, wherein the force required to secure and maintain adequate traction is independent from the force required to constrict or occlude the body tissue or vessel.

5. The medical device of claim 4, wherein only a compressive force needed to perform a specific surgical procedure such as occlusion, ligation or fixation is applied to the body tissue.

6. The medical device of claim 5, wherein tissue necrosis due to over-compression is eliminated.

7. The medical device of claim 1, wherein at least one of the first and the second tissue engaging-members 205, 210 includes a plurality of bumps, ridges, slots, and holes.

8. The medical device of claim 1, wherein the securing member 220 is a spring clip or a deformable clip acting as a retention member and providing uniform pressure across the occluded tissue or vessel.

9. The medical device of claim 2, wherein the first and the second connecting walls 234, 244 and the tissue-penetrating elements 238, 248 are formed as an integral, one-piece construction.

10. The medical device of claim 2, wherein the tissue-penetrating  
5 elements 238, 248 are formed in a plurality of rows.

11. The medical device of claim 10, wherein the number of tissue-  
penetrating elements 238, 248 per row and the number of rows vary according to  
each application.

12. The medical device of claim 10, wherein the tissue-penetrating  
elements 238, 248 are aligned or staggered.

13. The medical device of claim 2, wherein the tissue-penetrating  
elements 238, 248 and the securing member 220 have cross-sections of any  
configuration including polygonal, circular and elliptical configurations.

14. A medical device 500 to constrict or occlude a body tissue or vessel,  
comprising:

a first tissue-engaging portion 505 having a first face including a plurality  
of tissue penetrating elements or protrusions 525;

5 a second tissue-engaging portion 510 opposing the first tissue-engaging  
portion 505 having a second face including a plurality of tissue penetrating  
elements or protrusions 530; and

a deformable portion 520 connecting the first and the second tissue-  
engaging portions 505, 510.

10           15. The medical device of claim 14, wherein only a force required to perform a specific surgical procedure such as occlusion, ligation or fixation is applied to the body tissue or vessel.

16. The medical device of claim 15, wherein tissue necrosis due to over-compression is eliminated.

17. The medical device of claim 14, wherein the medical device is formed from a flat metal sheet that is die-cut, stamped or etched forming a first notched or tooled portion of the first tissue-engaging portion 505, a smooth connecting portion of the deformable portion 520 and a second notched or toothed portion of  
5 the second tissue-engaging portion 510.

18. The medical device of claim 17, wherein a plurality of notches or teeth of the first and the second portions are bent so as to extend in the same direction or plane and to form channels within the notches or teeth.

19. The medical device of claim 17, wherein the device is formed in a U-shape by bending the deformable portion 520 so that the notches or teeth of the first and the second tissue-engaging portions 505, 510 are opposed.



5           20. The medical device of claim 14, wherein the device is formed from any medically acceptable metal or plastic material that is ductile, malleable or deformable.

          21. The medical device of claim 20, wherein the metal includes titanium and stainless steel.

          22. An applier 600 for applying a medical device to constrict or occlude a body tissue or vessel, the device having a first tissue-engaging member 205 having opposed walls 230, 232 and a first connecting wall 234 defining a first elongate channel 236, a second tissue-engaging member 210 opposed to the  
5   first tissue-engaging member having opposed walls 240, 242 and a second connecting wall 244 defining a second elongate channel 246, and a securing member 220 for securing the first and the second tissue-engaging members 205, 210 such that front faces of the first and the second connecting walls 234, 244 are opposed to each other, the applier comprising:  
10           an elongate shaft 605 having a proximal end and a distal end 610;  
          a pair of opposed jaws 615, 620 connected at the distal end of the elongate shaft 605;  
          a handle operably connected at the proximal end of the elongate shaft 605 to open and close the opposed jaws 615, 620; and

15           a sliding member 625 operably connected within the elongate shaft 605 to advance the securing member 220 over the first and the second tissue-engaging members 205, 210 after closure of the jaws 615, 620.

23. The applier of claim 22, wherein the jaws 615, 620 operate to apply the first and the second tissue-engaging members 205, 210 around a target body tissue or vessel.

24. The applier of claim 23, wherein the first and the second tissue-engaging members 205, 210 are applied to the jaws 615, 620 either manually or automatically.

25. The applier of claim 23, wherein the jaws 615, 620 are compressed using only a force required for a specific surgical procedure such as occlusion, ligation or fixation.

26. The applier of claim 25, wherein the first and the second tissue-engaging members 205, 210 and the securing member 220 are introduced to a surgical site in an un-assembled condition through a small port or trocar.

27. The applier of claim 26, wherein the sliding member 625 operates to urge the securing member 220 forward and over the first and second tissue-engaging members 205, 210 to secure the medical device.

28. The applier of claim 27, wherein the applier and the medical device are sized and configured for use in a minimally invasive or laparoscopic surgical procedure.

29. The applier of claim 22, further comprising a plurality of slots in each of the opposed jaws 615, 620 to receive a plurality of the medical devices or multiple staple-clips to simultaneously apply the medical devices or staple-clips.

30. The applier of claim 29, further comprising a cutting member to be advanced between the medical devices or staple-clips after they have been applied to transect the body tissue or vessel between the medical devices or staple-clips.

31. A clip applier 850 for applying a clip to constrict or occlude a body tissue or vessel, the clip having a first arm 880 including a latch mechanism 890 at a distal end and a second arm 885 folded over the first arm 880 at a distal end and configured to interlock or mate with the latch mechanism 890 of the first arm 880, the applier comprising:

a handle 885 for storing the clip; and

a thumb actuated mechanism 860 operably slidable along the handle 885 by sliding the thumb actuated mechanism 860 forward 870a and backward 870b to release the clip.

10            32. The clip applier of claim 31, wherein the handle 855 further comprises a reservoir for storing a plurality of clips 865.

33. The clip applier of claim 32, wherein the plurality of clips 865 are strung end-to-end in a clip sleeve 892 suspended through an end port.

34. The clip applier of claim 33, wherein the plurality of clips 865 are formed from a single piece of material.

35. A clip 875 to constrict or occlude a body tissue or vessel, comprising:  
a first arm 880 including a latch mechanism 890 at a distal end; and  
a second arm 885 folded over the first arm 880 at a distal end and  
configured to interlock or mate with the latch mechanism 890 of the first arm 880.

36. The clip of claim 35, wherein the latch mechanism 890 is a hook.

37. The clip of claim 36, wherein at least one of the first and the second arms 880, 885 includes tissue-penetrating elements 898 or securing elements 1023, 1024 on an inner face.

38. The clip of claim 35, further comprising a third arm 899 connecting the first arm 880 and the second arm 885.

39. A clamp 950 to constrict or occlude a body tissue or vessel, comprising:

a tubular section 955 having an opening 960 extending from a proximal end 965 to a distal end 970; and

5 a lead-in wire 975 operably attached to the proximal end 965 and is movable between an open position and a closed position,

wherein in the closed position, the lead-in wire 975 is slidably received and secured in the opening 960 of the tubular section 955.

40. The clip of claim 39, wherein the lead-in wire 975 is bent against a wall of the tubular section 955 to further secure the body tissue or vessel.

41. The clip of claim 39, wherein the clamp is used in donor nephrectomy.

42. A medical device 1010 to constrict or occlude a body tissue or vessel, comprising:

a clip 1011 formed from a first wire including opposed arms 1013, 1014 and openings 1015, 1916; and

5           a staple 1012 for securing the clip 1011, the staple 1012 formed from a second wire having legs 1017, 1018 to puncture the body tissue or vessel and to interlock the clip 1011 through the openings 1015, 1016.

43. The medical device of claim 42, wherein the arms 1013, 1014 further comprise a latch mechanism at their distal ends to mate with each other when the arms 1013, 1014 are closed or clamped together.

**ABSTRACT OF THE DISCLOSURE**

A surgical staple-clip including a clip component and a securing member is used in a wide range of surgical procedures. The staple-clip may be introduced to a surgical site in an un-assembled condition through a small port or trocar. An applier for the staple-clip comprising a pair of opposed jaw-like channels is provided to position and apply the clip component and the securing member. The clip component is positioned around a target tissue and is compressed or clamped upon the tissue using only the force required for a specific surgical procedure such as occlusion, ligation or fixation. When the clip component is properly applied, the securing member is urged forward and over the clip component to secure the staple-clip. The clip component may include traction enhancement features such as surface interruptions, bumps, valleys and ridges. With the staple-clip of the invention, the force required to constrict or occlude the tissue is separate from the force required to secure and maintain the staple-clip in position and, as a result, the body tissue is not over-compressed and nourishment to the body tissue is maintained. Other aspects of the invention include thumb actuated clip appliers for use in hand assisted laparoscopy (HAL). In one embodiment, a clip applier includes a handle and a thumb actuated mechanism that is used to slidably release clips onto a body tissue or vessel by sliding the thumb actuated mechanism forward and backward using only one hand. In another aspect of the invention, a two-stage clip is disclosed having a clip component and a staple component for securing the clip after it has been properly positioned.

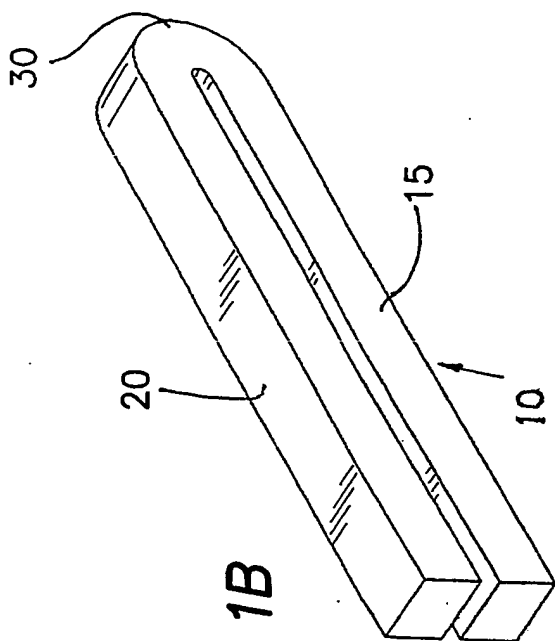


FIG. 1B

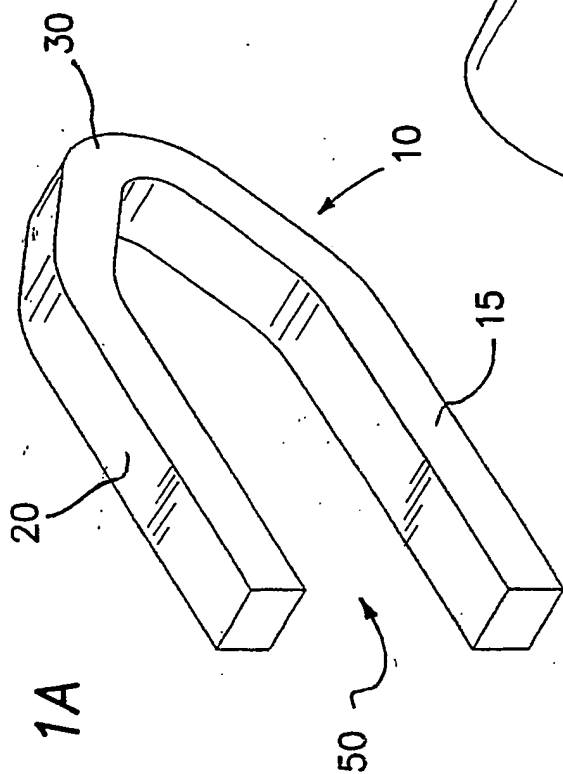


FIG. 1A

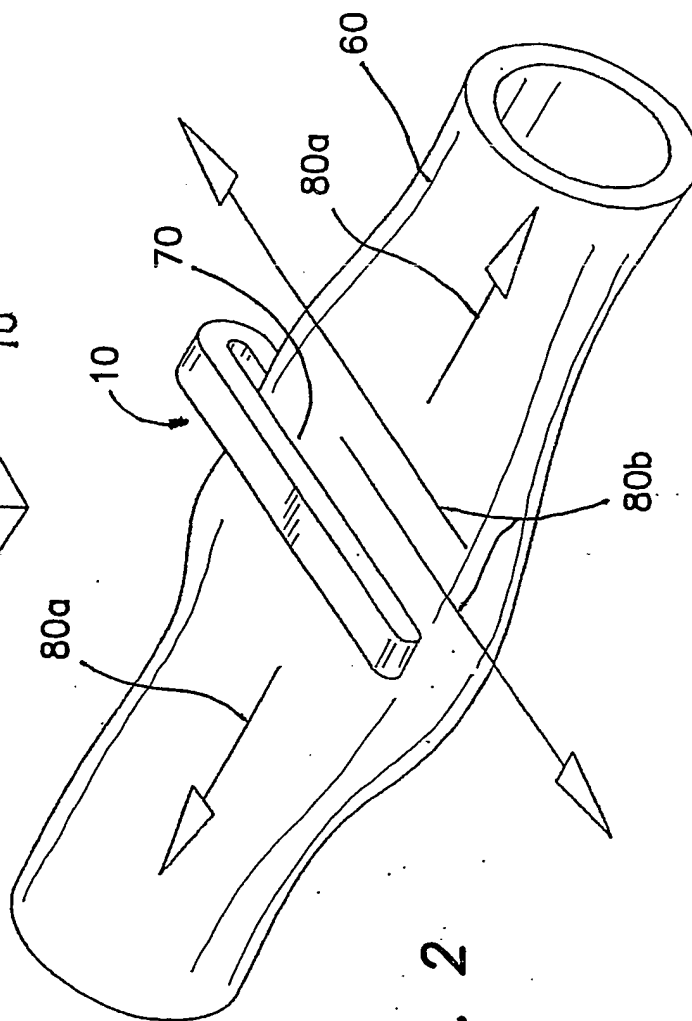


FIG. 2



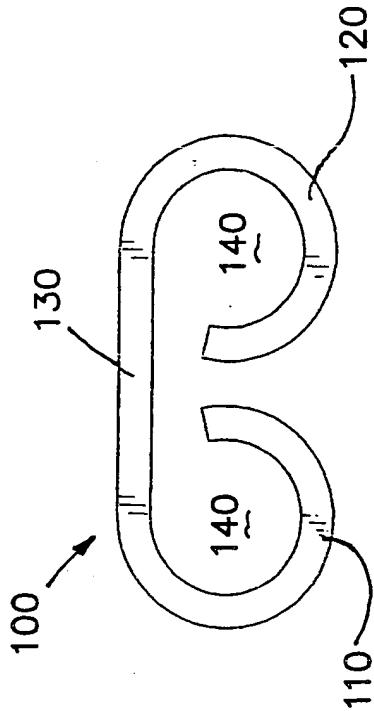


FIG. 3B

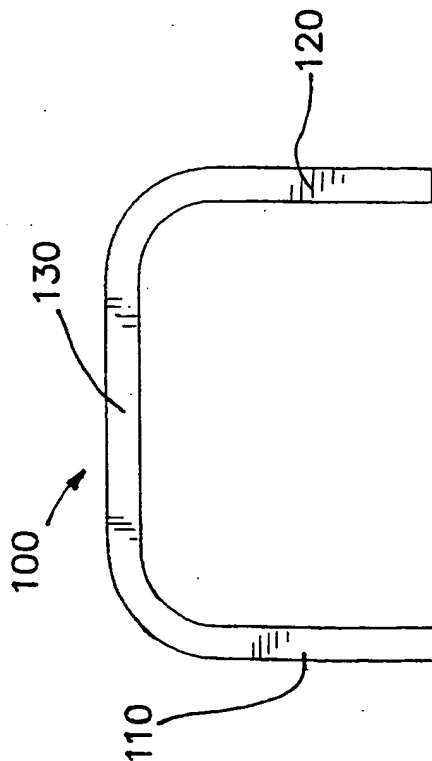


FIG. 3A

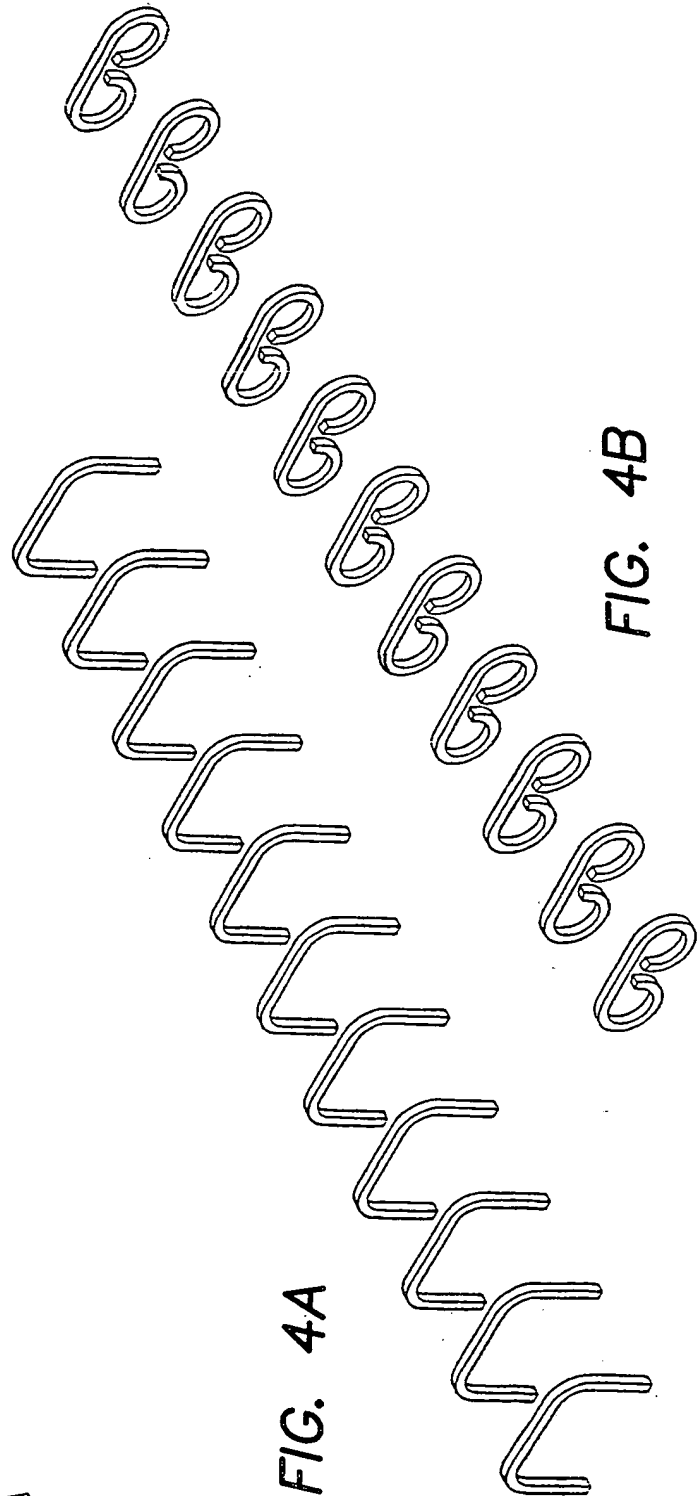
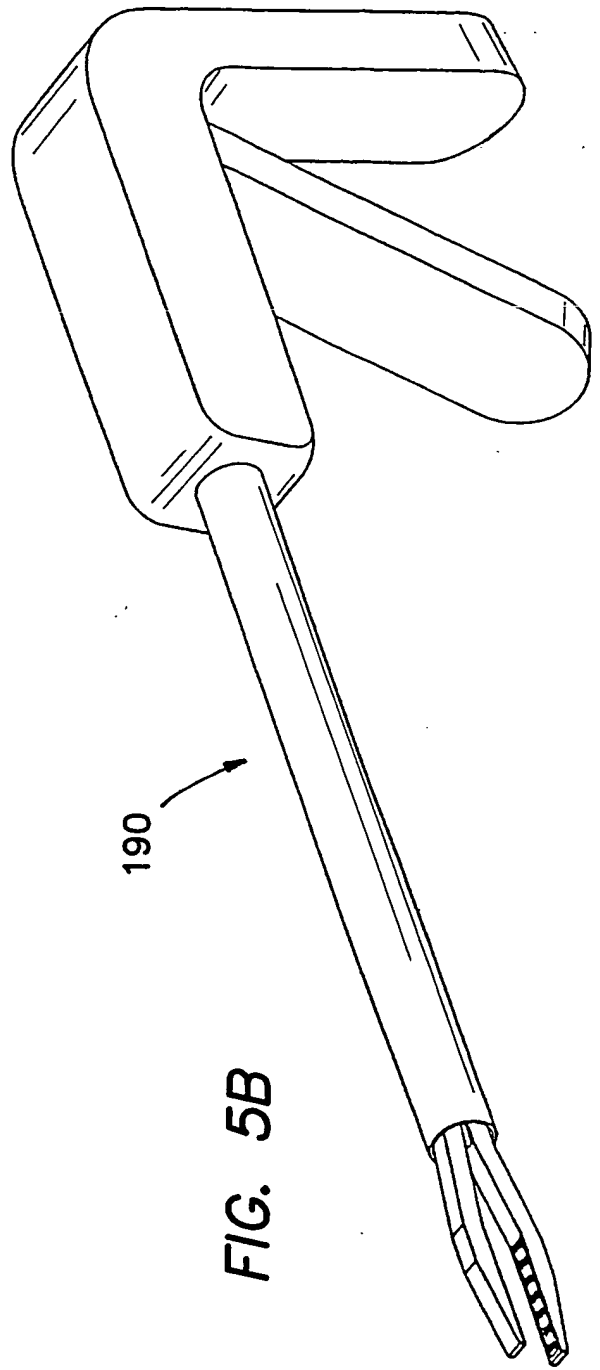
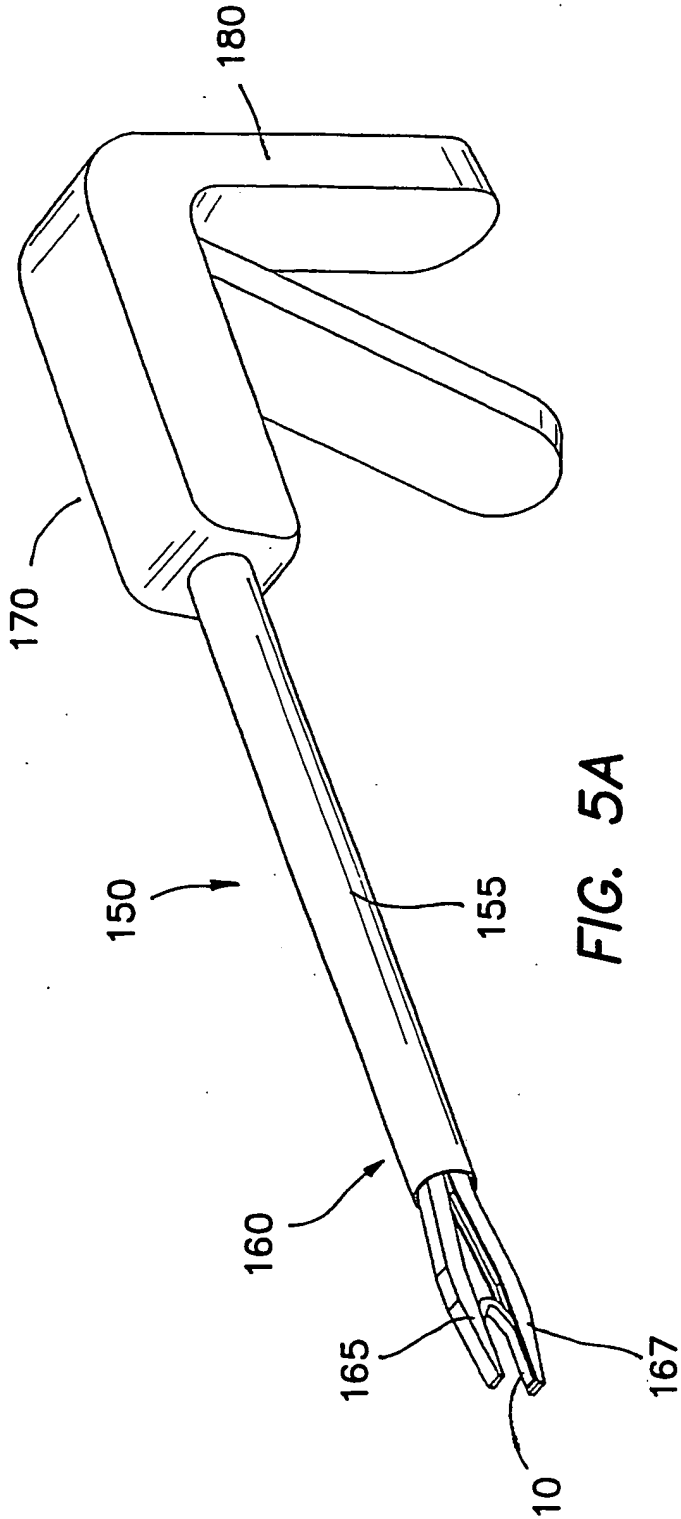
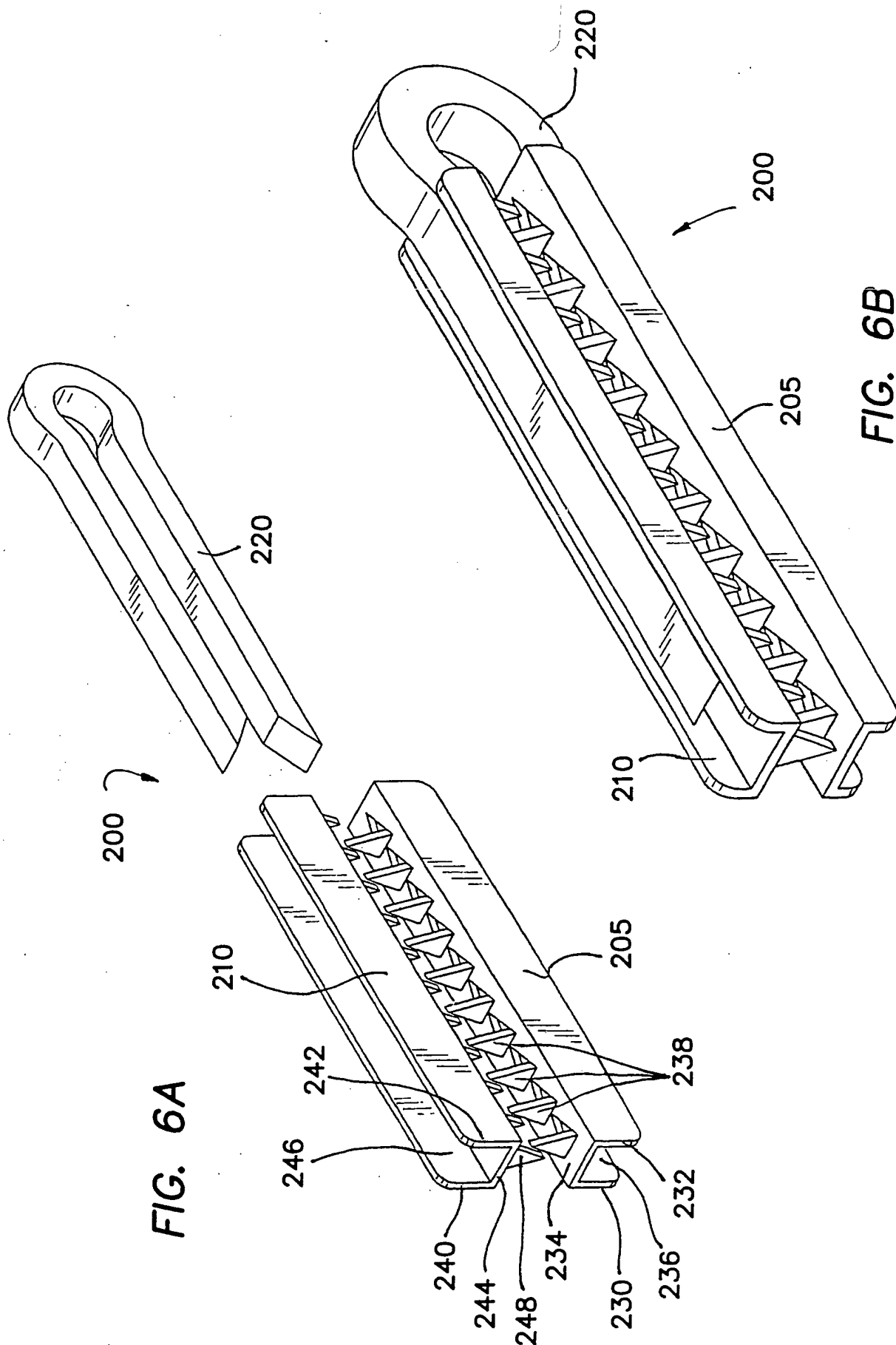
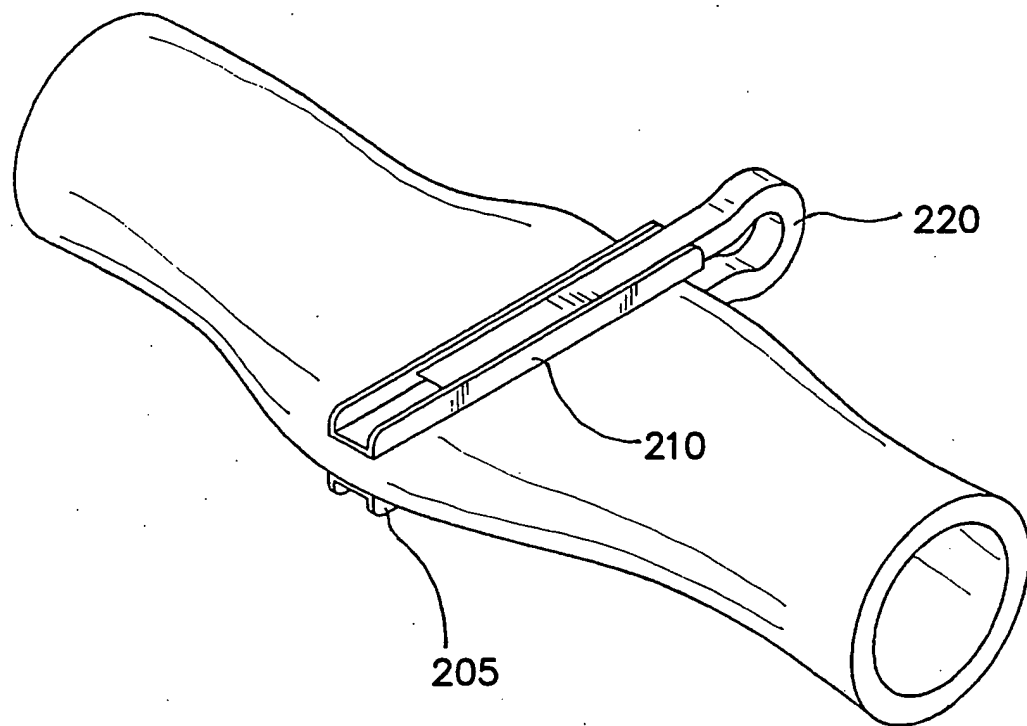


FIG. 4A

FIG. 4B

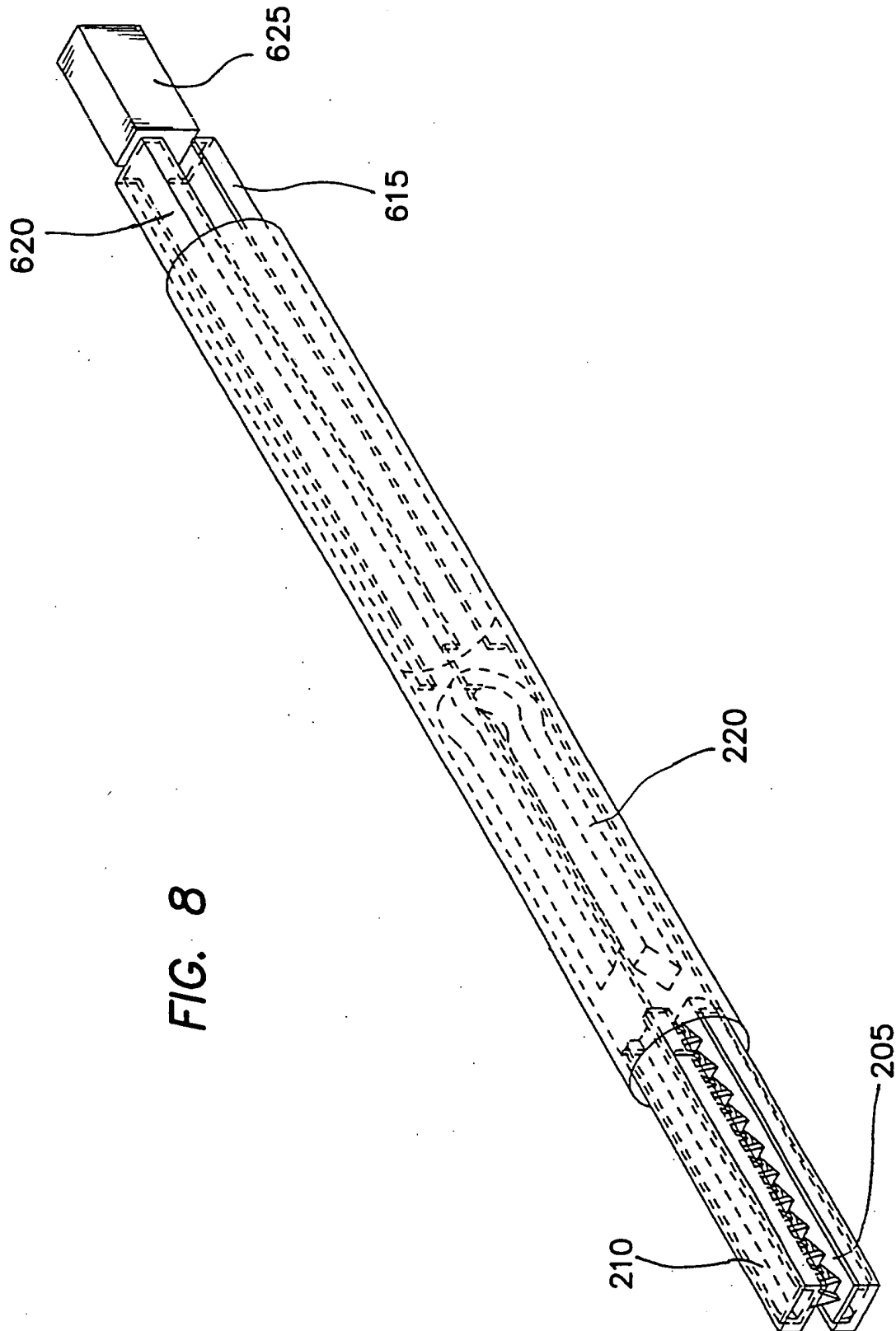






**FIG. 7**

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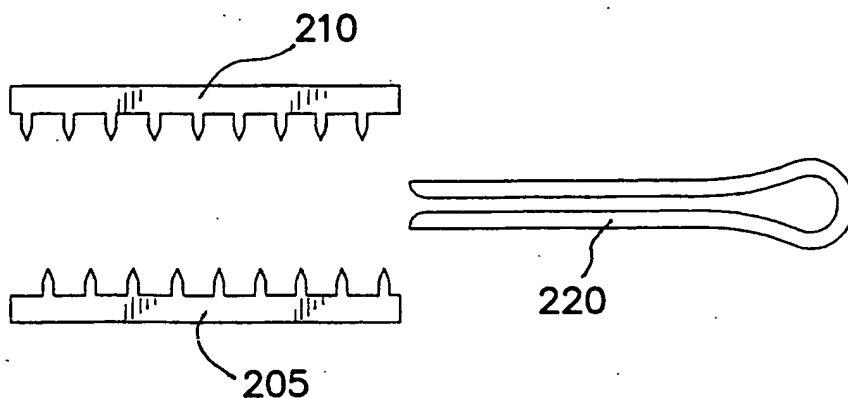


FIG. 9A

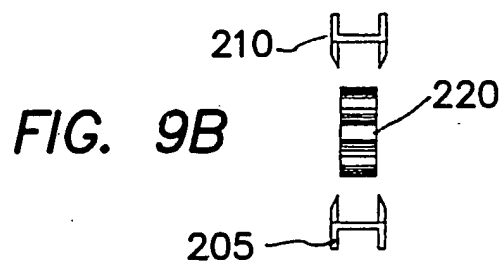


FIG. 9B

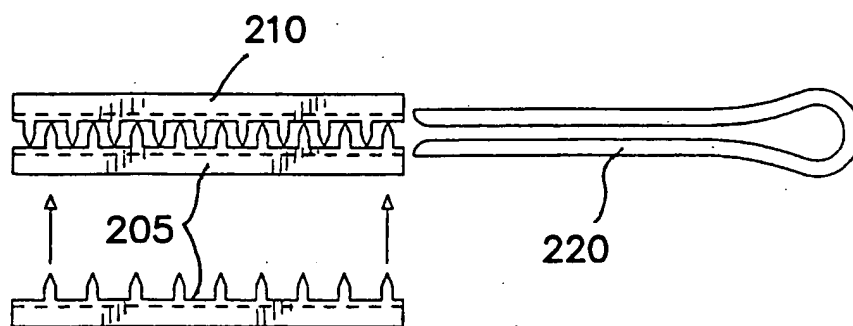


FIG. 9C

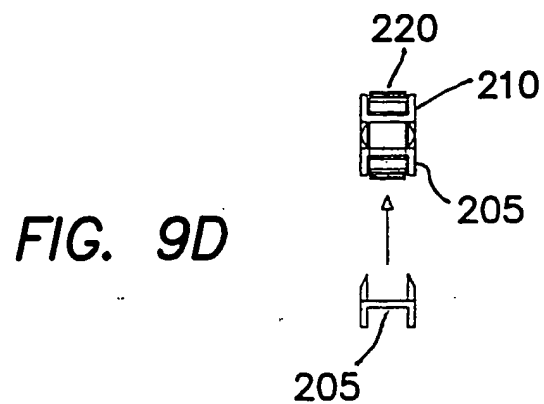


FIG. 9D

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Applicant: Charles C. Hart  
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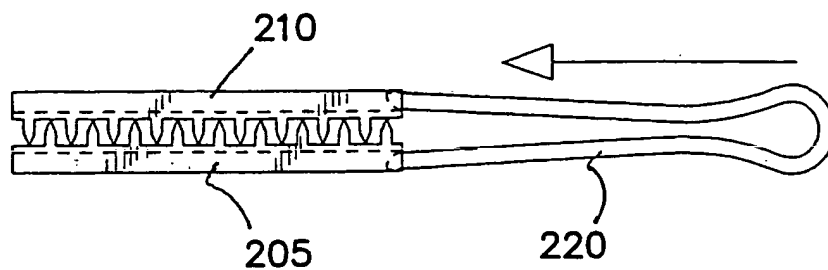


FIG. 9E

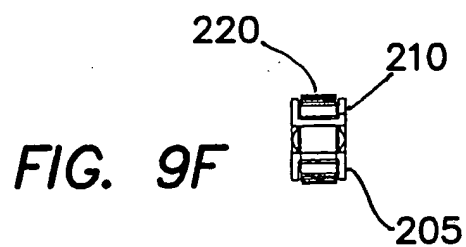


FIG. 9F

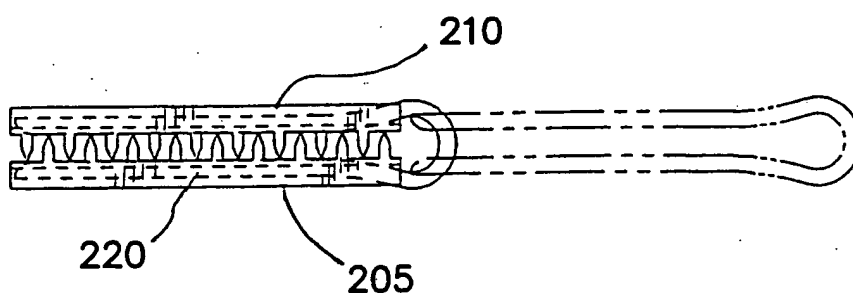


FIG. 9G

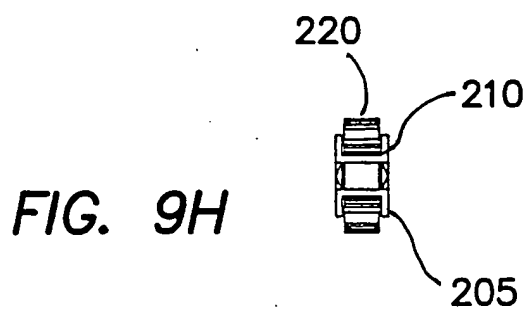
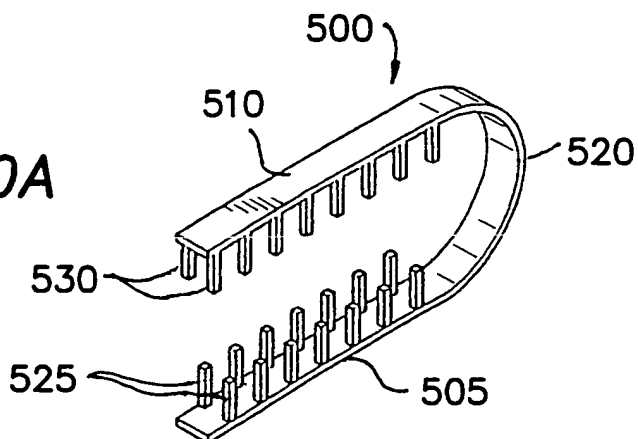
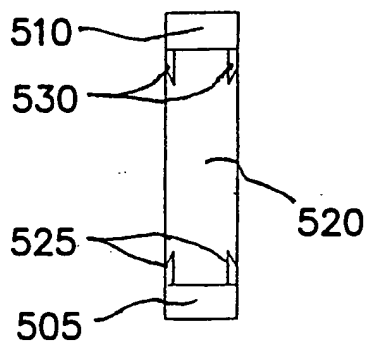
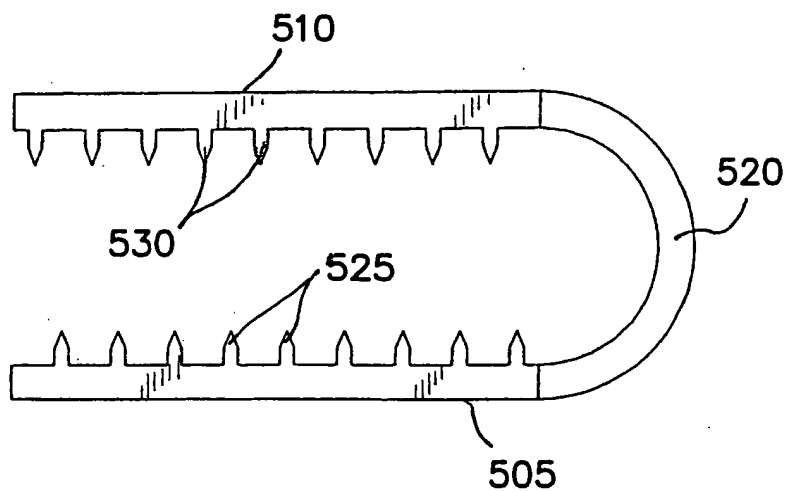
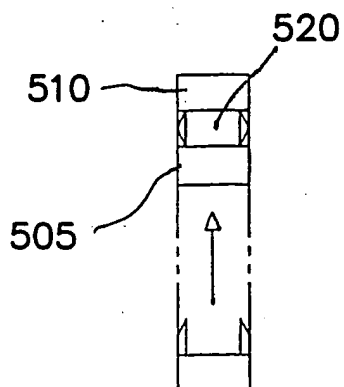
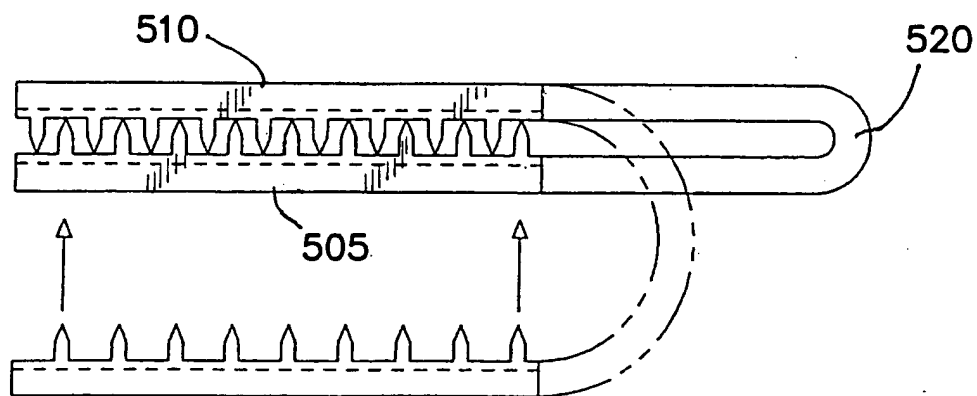
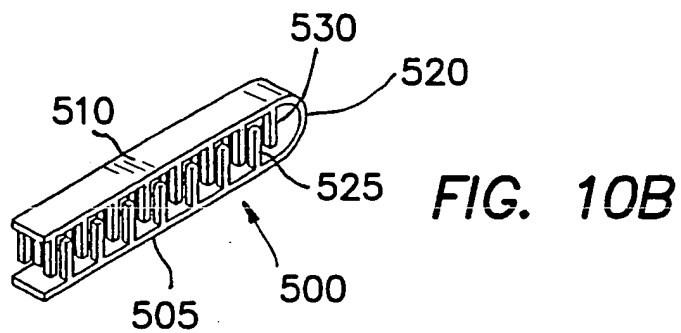


FIG. 9H

**FIG. 10A****FIG. 10C****FIG. 10E**





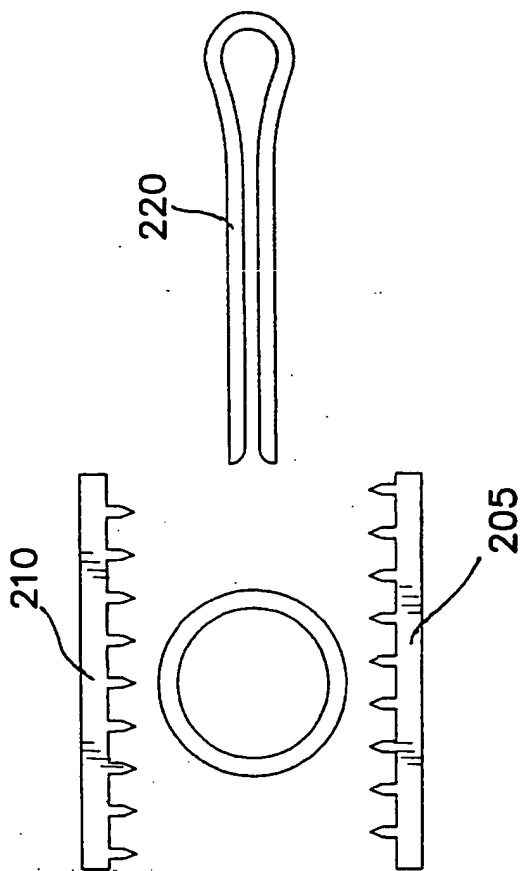


FIG. 11A

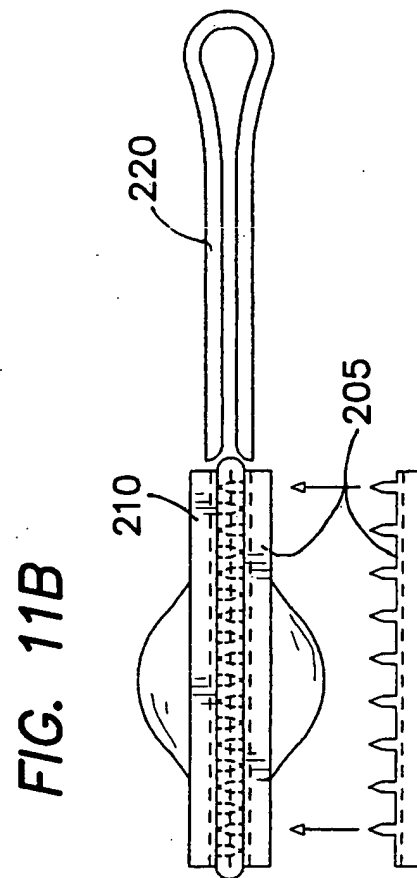


FIG. 11B

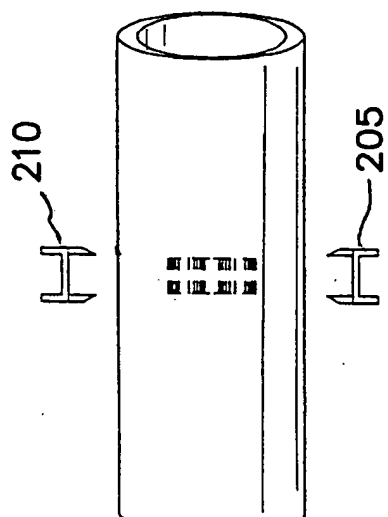


FIG. 11C

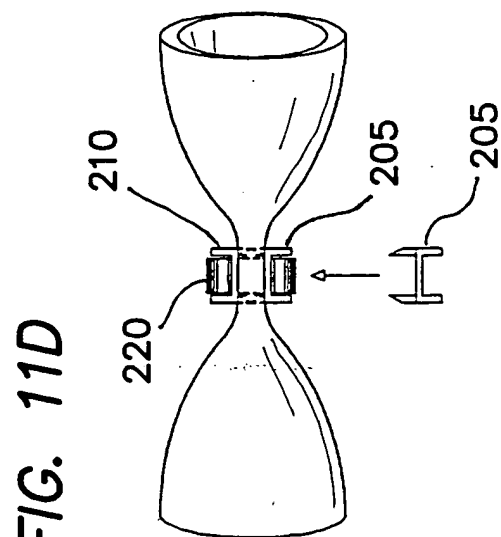


FIG. 11D

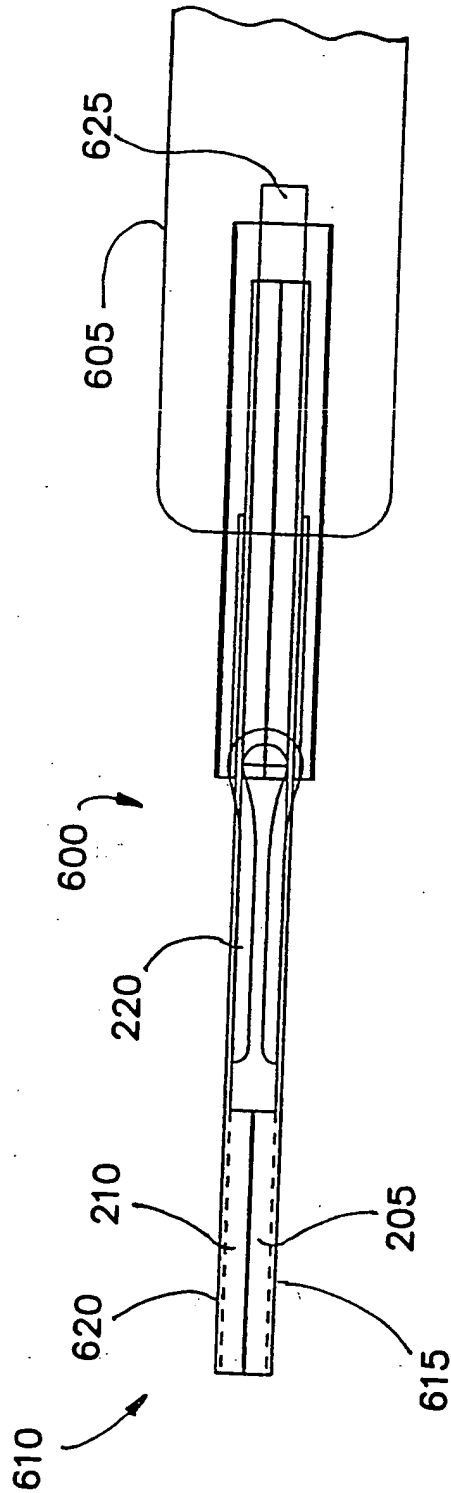


FIG. 12A

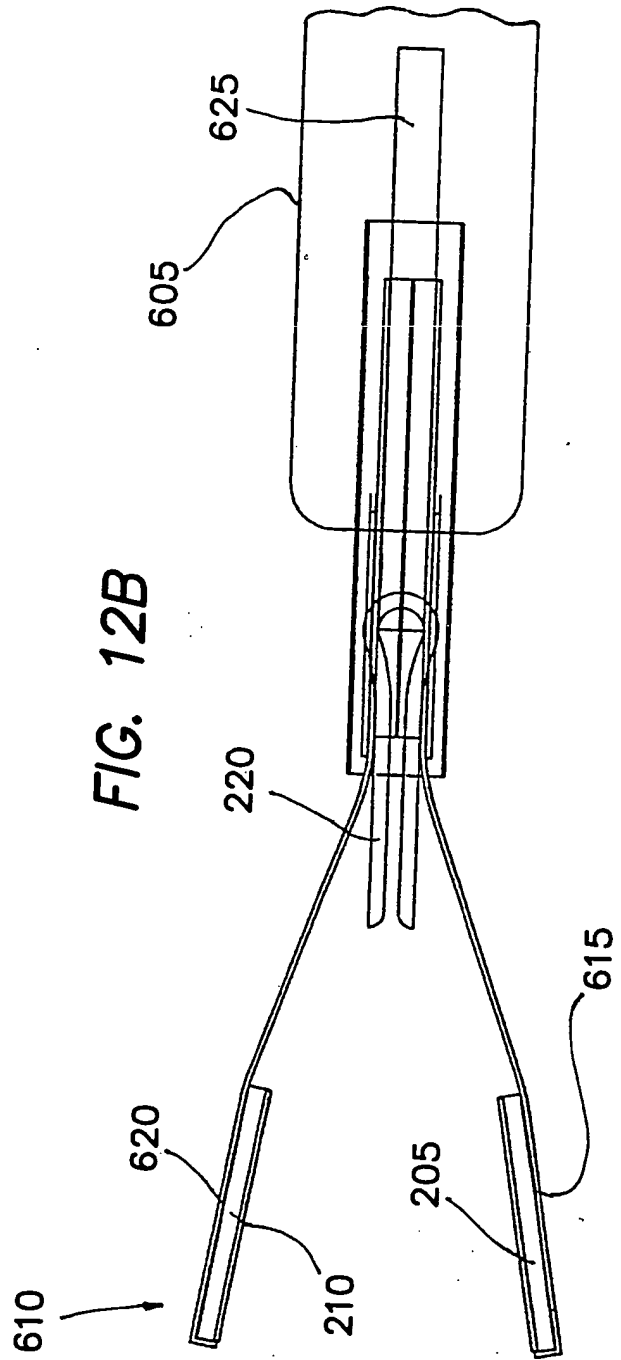


FIG. 12B



FIG. 12C



FIG. 12D

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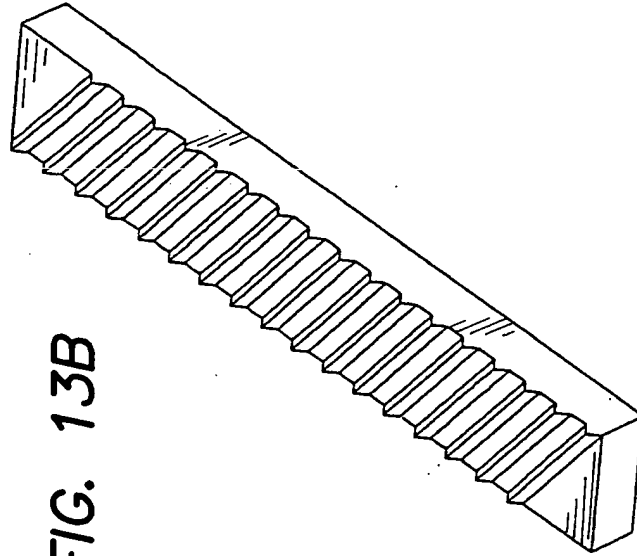


FIG. 13B

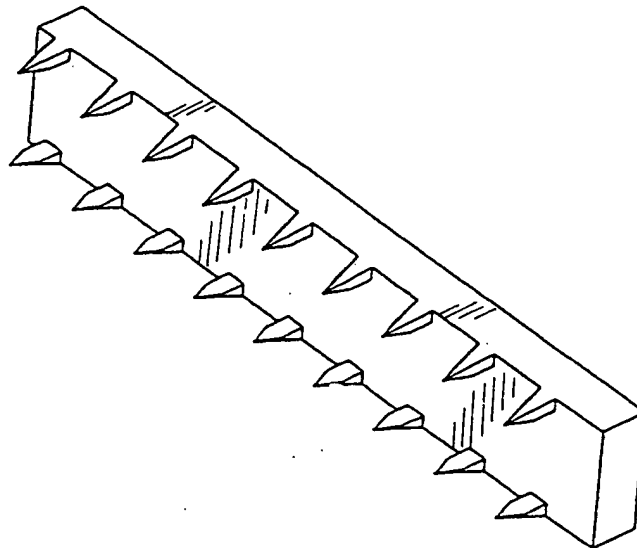


FIG. 13A

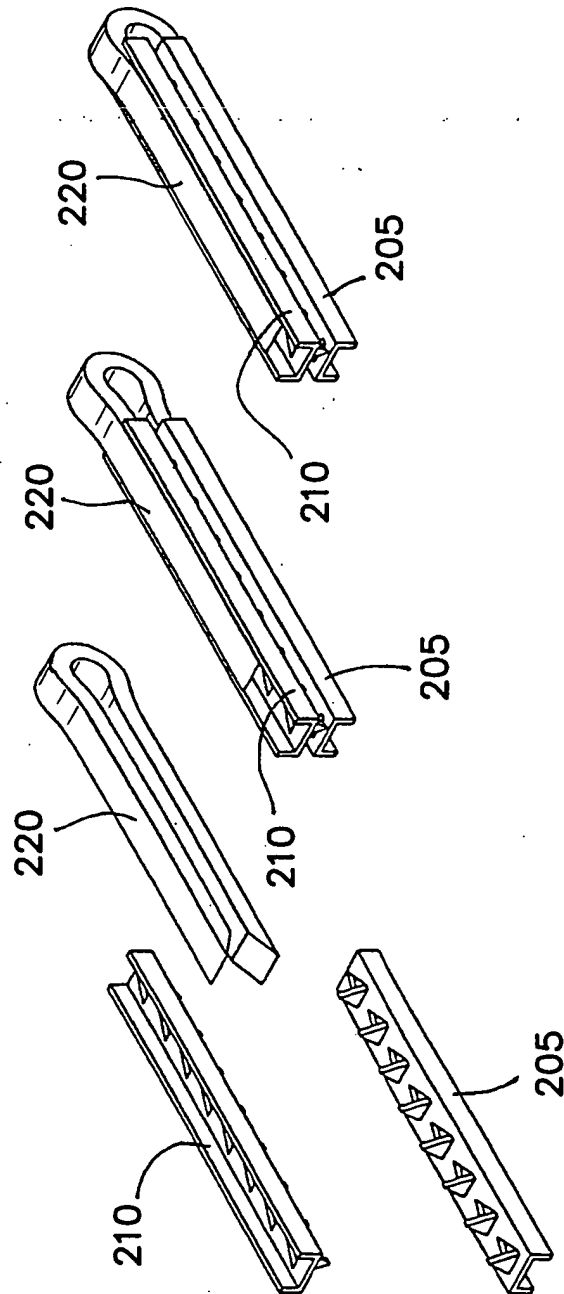
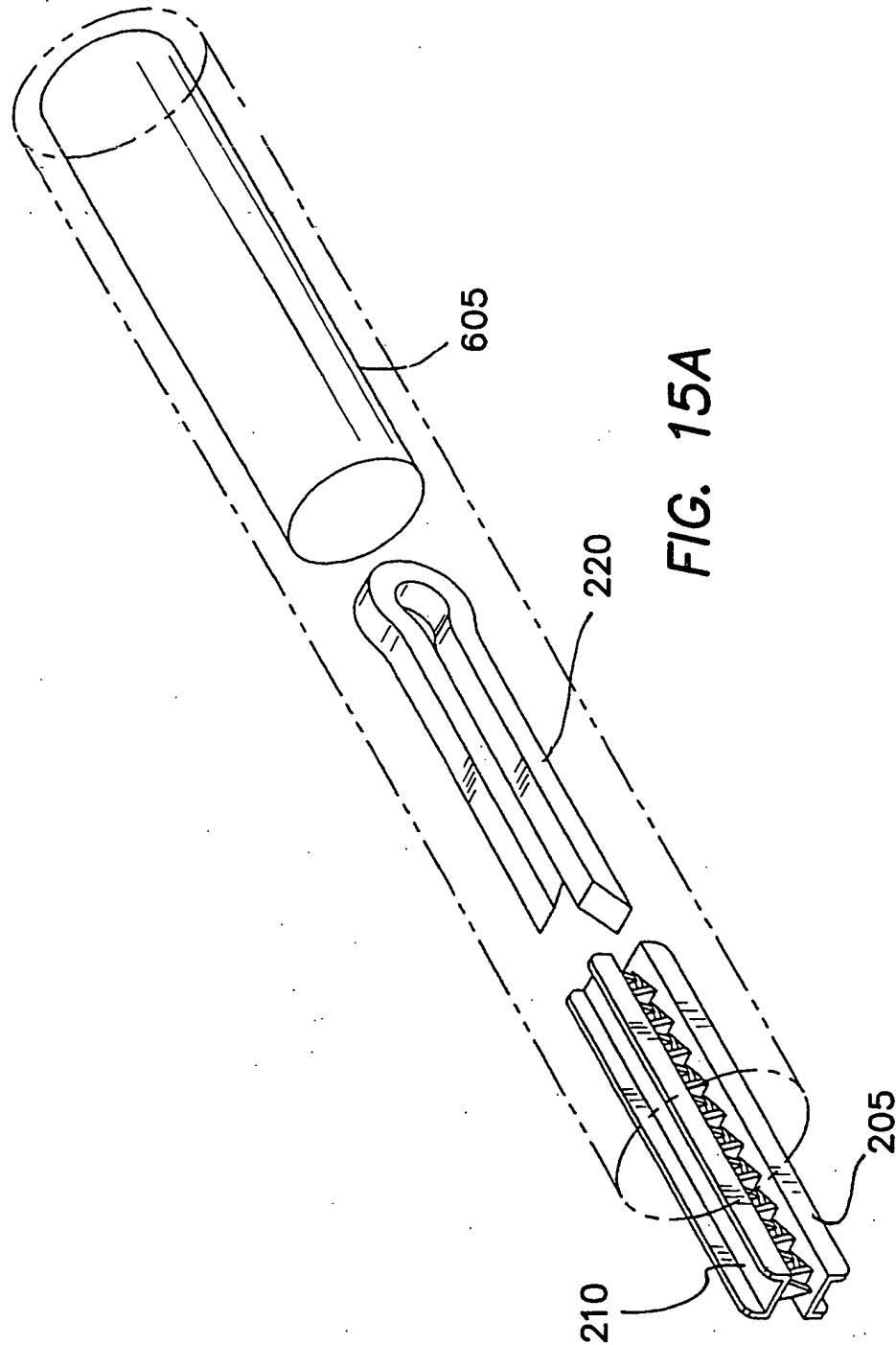
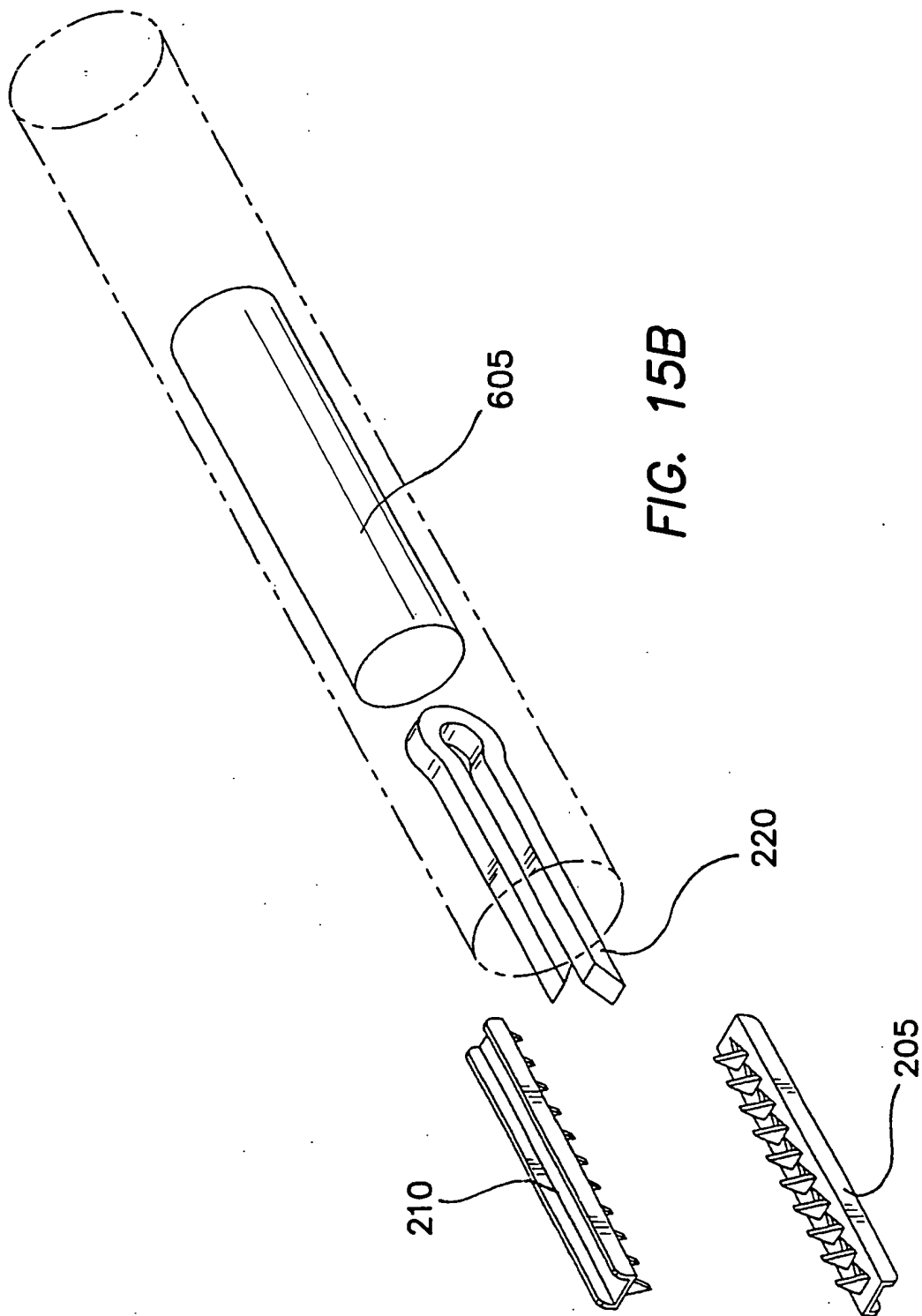
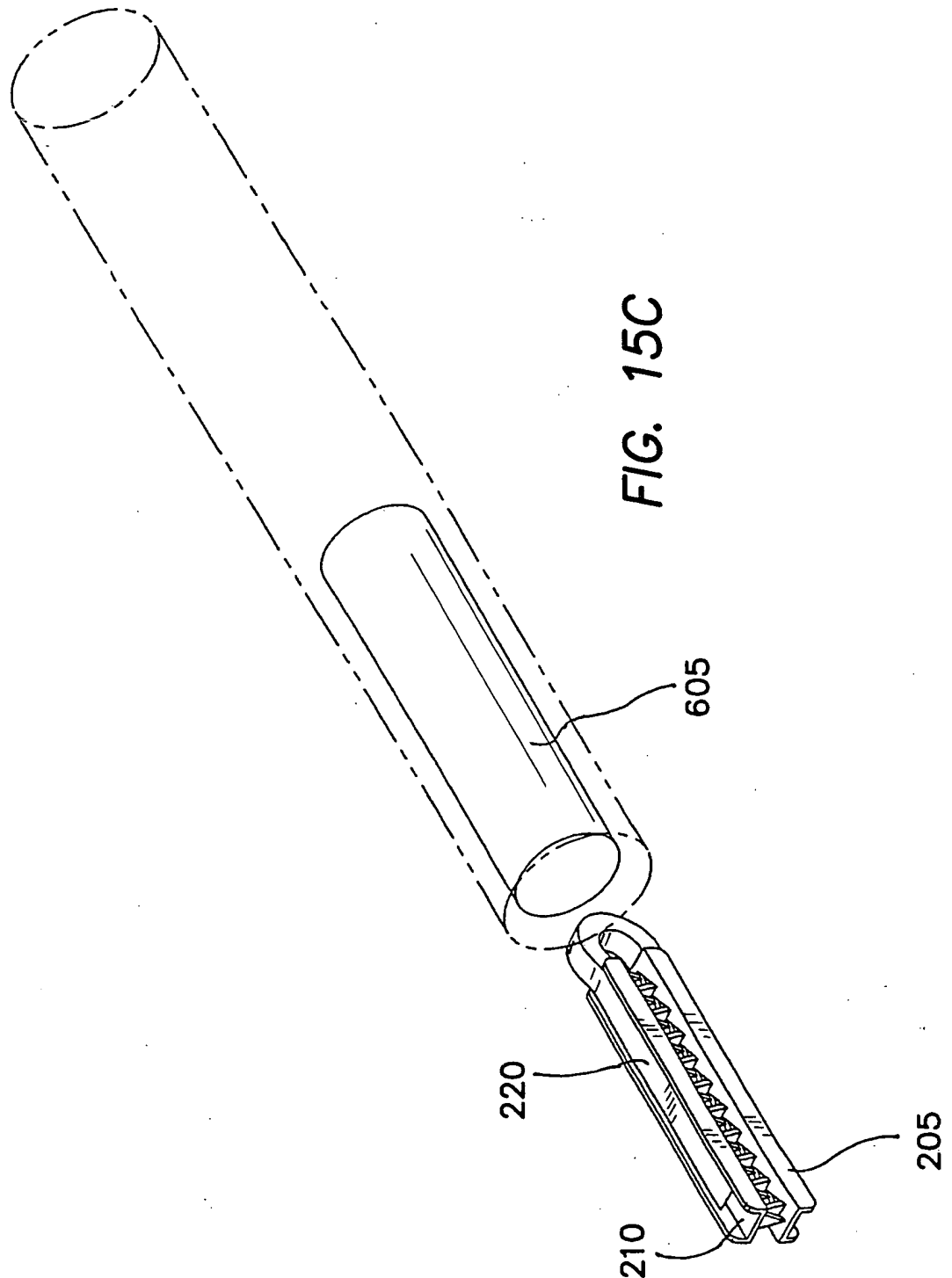


FIG. 14



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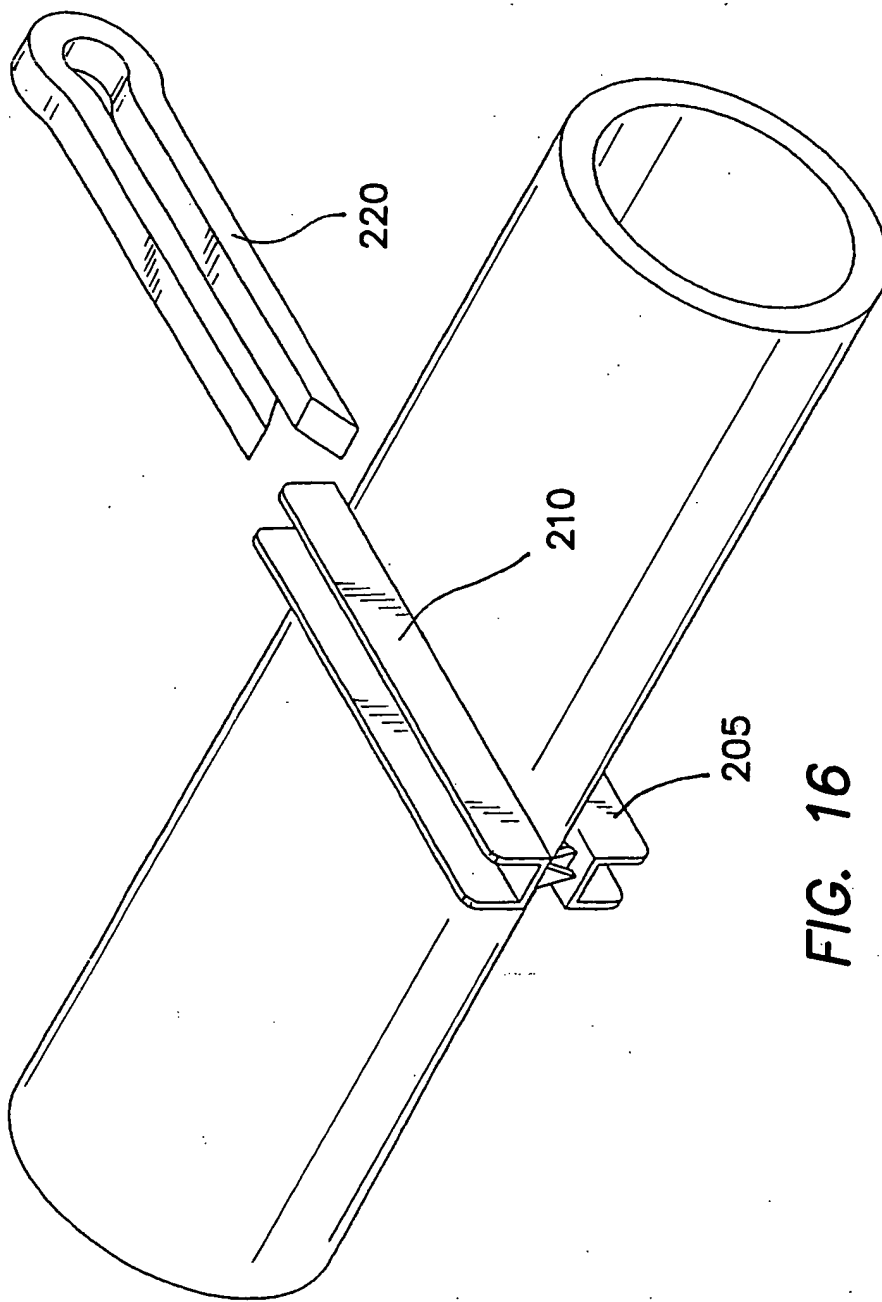
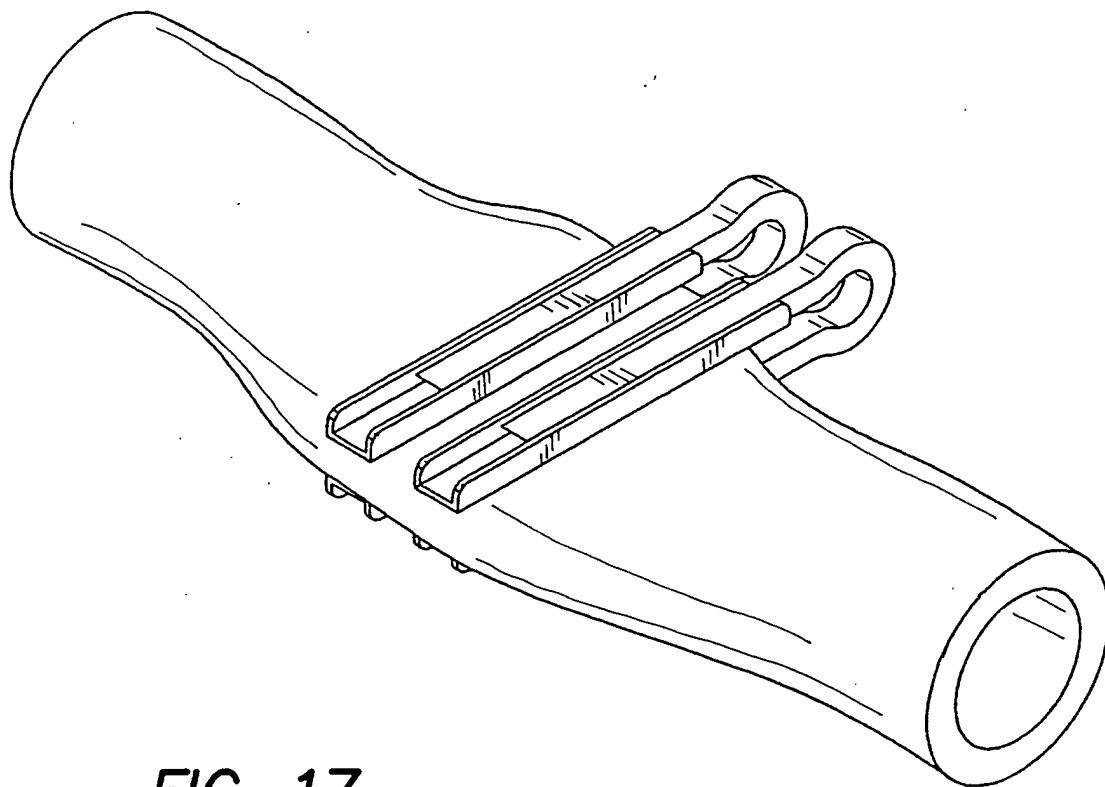


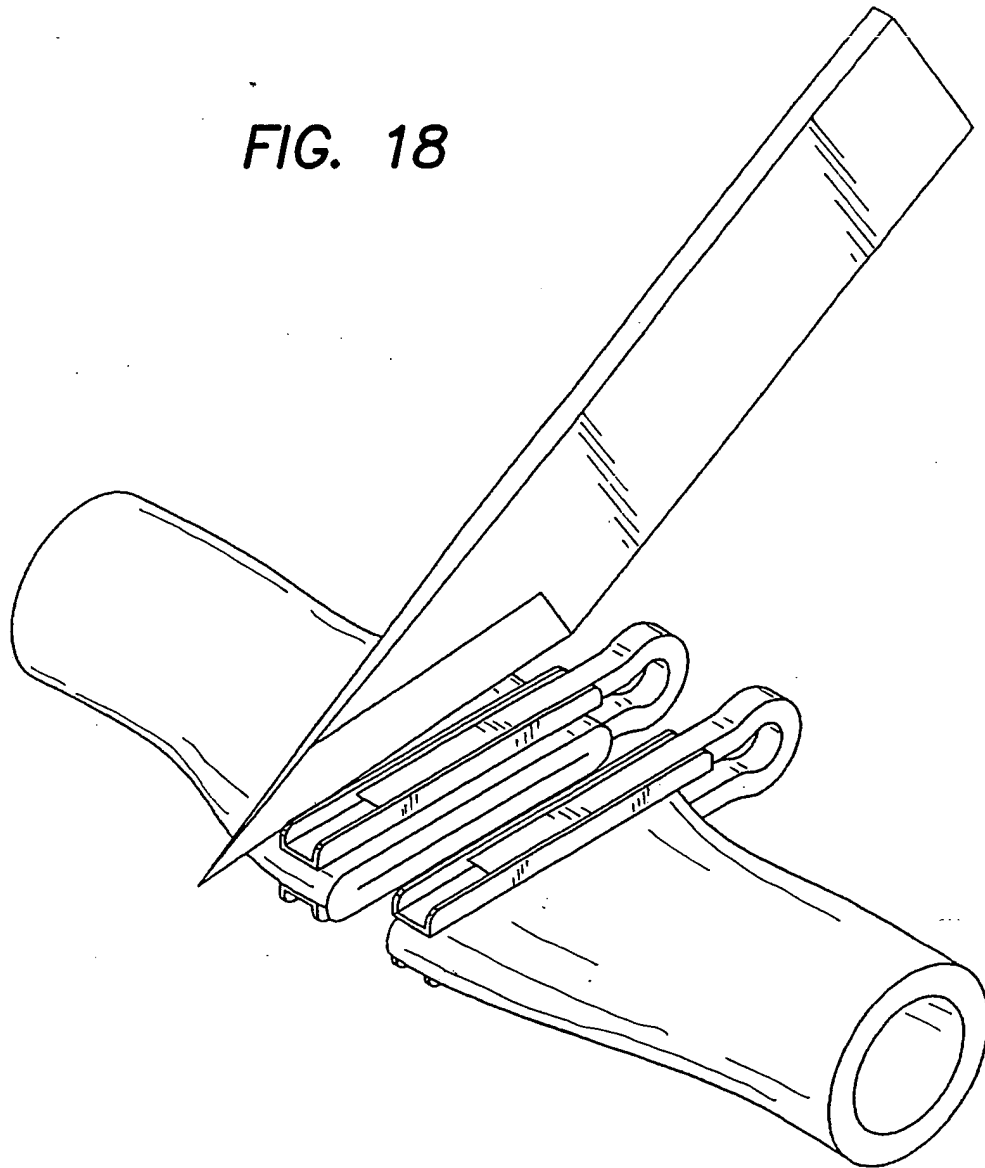
FIG. 16

Title: Surgical Staple-Clip Applier  
Applicant: Charles C. Hart  
Application No.: Not yet Assigned  
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**FIG. 17**

**FIG. 18**



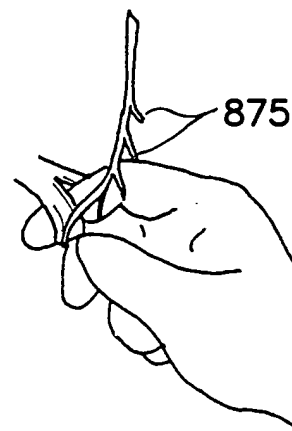
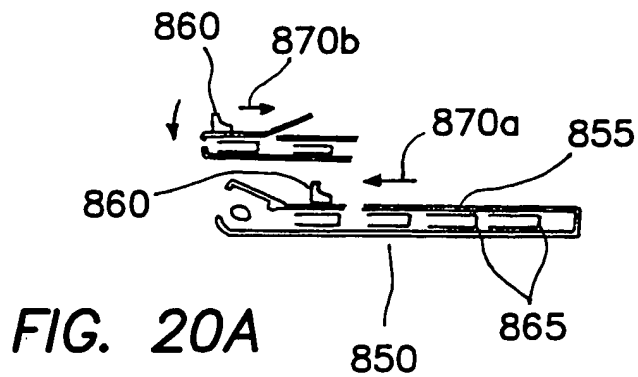
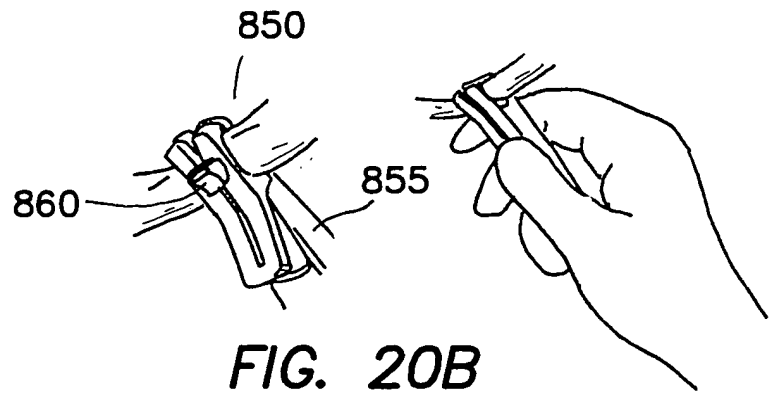
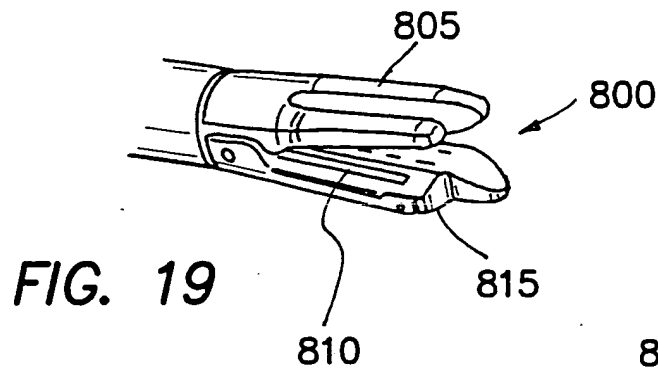
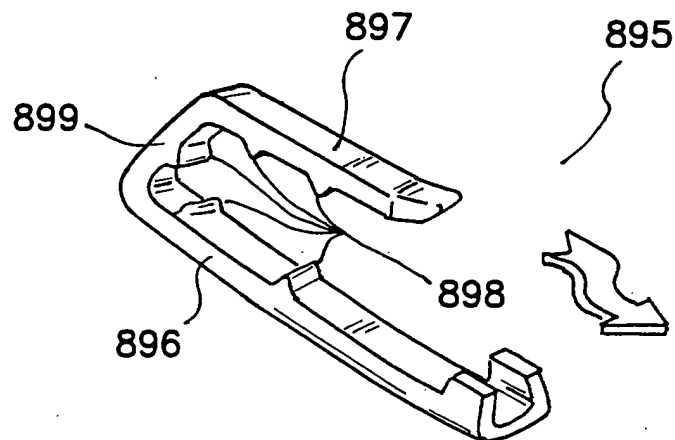
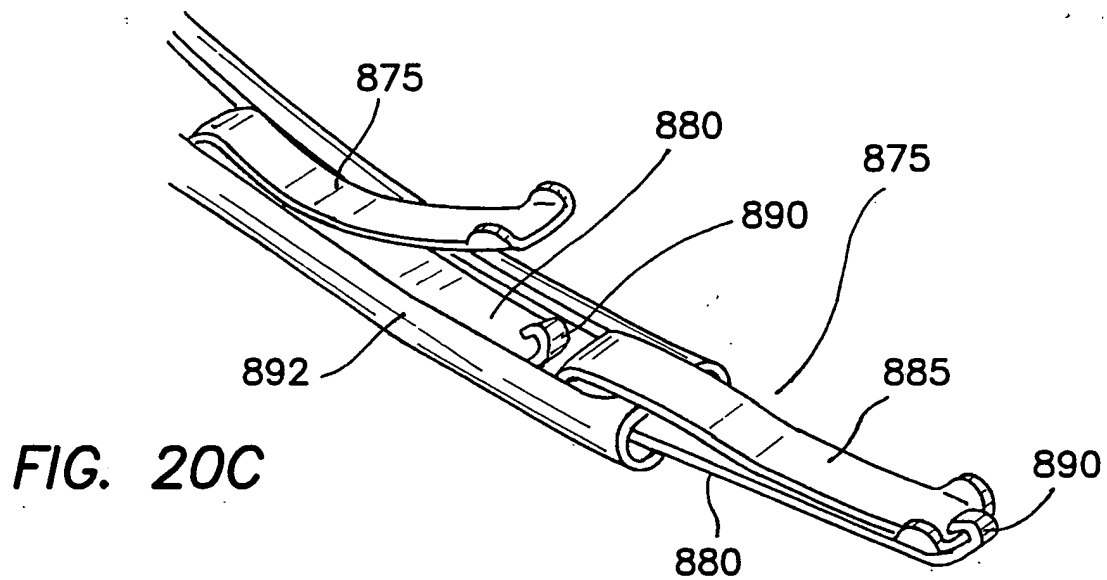
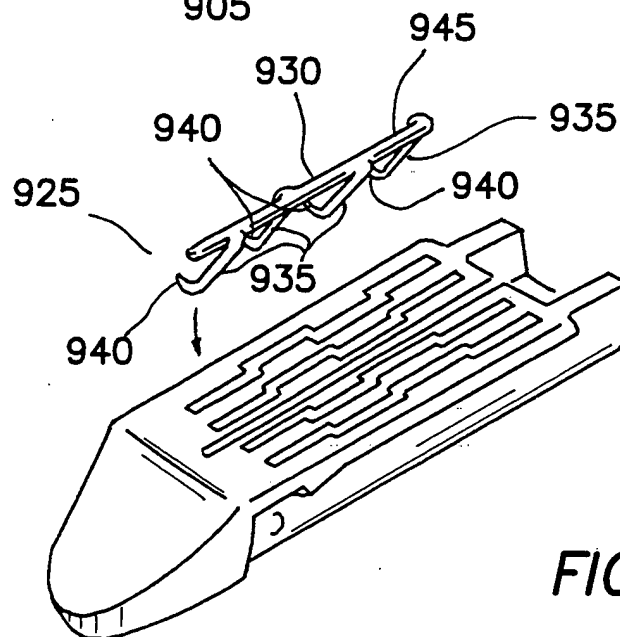
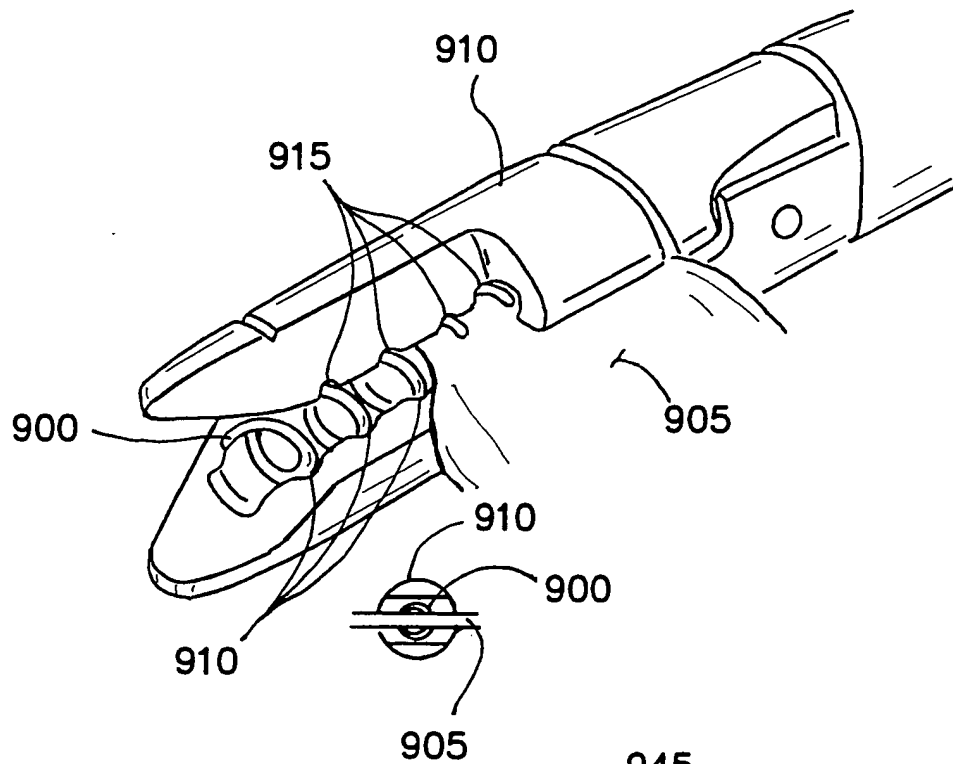


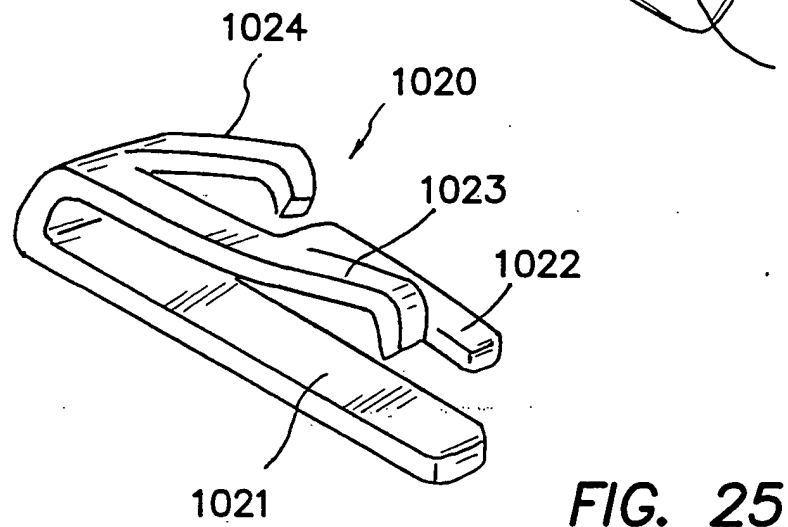
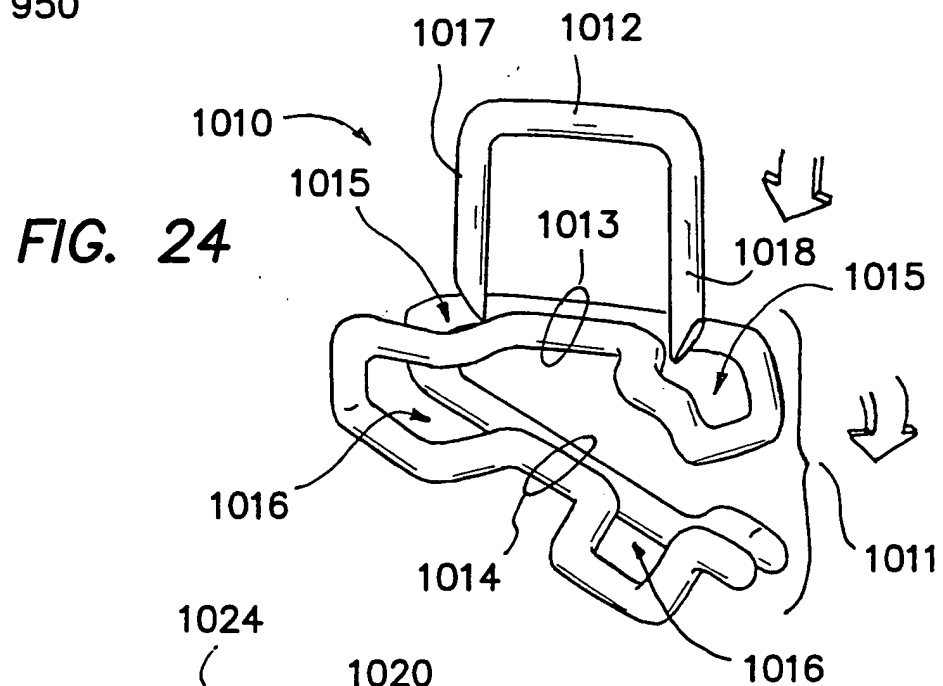
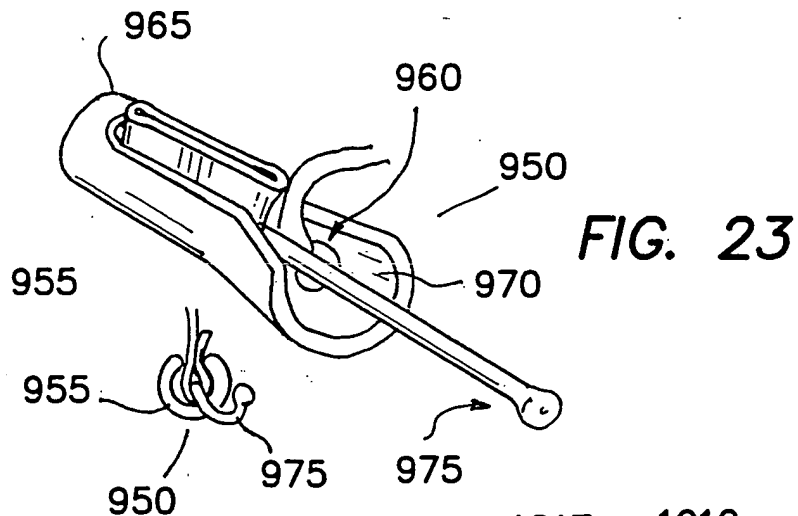
FIG. 20D

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**FIG. 21****FIG. 22**



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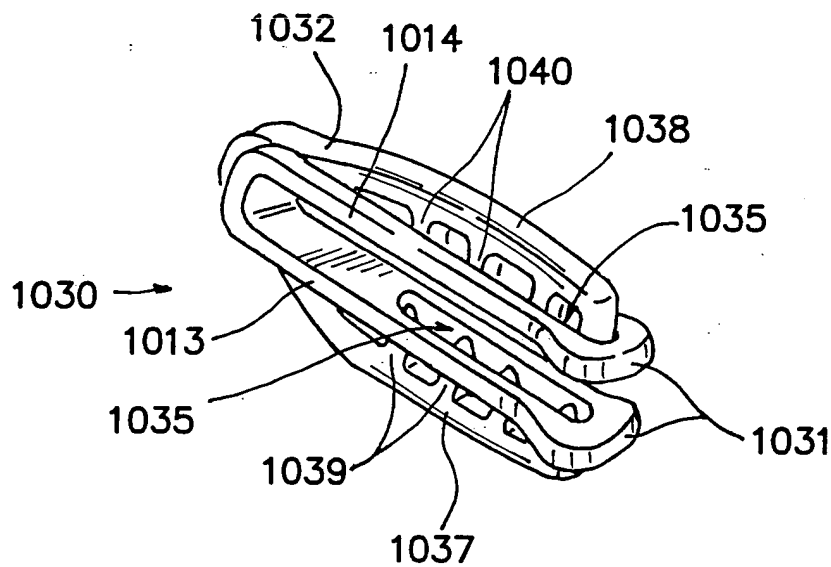


FIG. 26

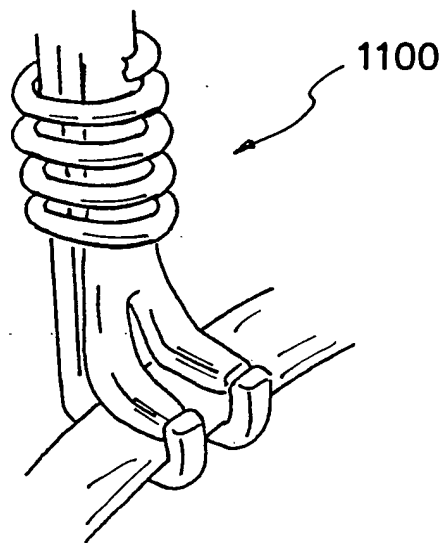


FIG. 27